EXHIBIT 32

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1
              IN THE UNITED STATES DISTRICT COURT
               FOR THE NORTHERN DISTRICT OF OHIO
 2
                       EASTERN DIVISION
 3
    IN RE: NATIONAL PRESCRIPTION ) No. 17-md-2804
   OPIATE LITIGATION NO. 2804
 4
 5
  APPLIES TO ALL CASES
                                     ) Hon. Dan A. Polster
6
7
          HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
8
                   CONFIDENTIALITY REVIEW
9
               VIDEO DEPOSITION OF JOHN GILLIES
10
                       February 7, 2019
11
                           9:07 a.m.
12
                      HIGHLY CONFIDENTIAL
           SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
13
14
           Reporter: John Arndt, CSR, CCR, RDR, CRR
15
                      CSR No. 084-004605
                         CCR No. 1186
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| | Page 2 | | Page 4 |
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| 1 2 3 4 | DEPOSITION OF JOHN GILLIES produced, sworn, and examined on January 7, 2019, at Bryan Cave Leighton Paisner LLP, 211 North Broadway, Suite 3600, in the City of St. Louis, State of Missouri, before John Arndt, a Certified Shorthand Reporter and Certified Court Reporter. | 3 4 | INDEX OF INTERROGATION Examination by Mr. Ko Page 9 Examination by Ms. Herzfeld Page 274 Examination by Mr. O'Connor Page 326 INDEX OF EXHIBITS |
| 5 6 | APPEARANCES OF COUNSEL On Behalf of Plaintiffs: | 5 6 | Exhibit Mallinckrodt-Gillies-001 Page 12 (Notice of deposition) |
| 7 8 9 | Keller Rohrback LLP 1201 Third Avenue, Suite 3200 Seattle, WA 98101 (206) 623-1900 BY: MR, DAVID J. KO | 8 | Exhibit Mallinckrodt-Gillies-002 Page 52 (E-mail chain with attachment) (MNK-T1_0000273575 - MNK-T1_0000273582) |
| 10 | dko@kellerrohrback.com MS. ALISON S. GAFFNEY agaffney@kellerrohrback.com | 10 | Exhibit Mallinckrodt-Gillies-003 Page 52 (DEA letter) (MNK-T1_0000270069 - MNK-T1_0000270070) |
| 12 | MR. DEAN KAWAMOTO dkawamoto@kellerrohrback.com On Behalf of Tennessee Action: | 11 | Exhibit Mallinckrodt-Gillies-004 Page 80 (E-mail message) (MNK-T1_0001806623) |
| 13 14 15 | Branstetter, Stranch & Jennings, PLLC 223 Rosa L. Parks Avenue, Suite 200 Nashville, TN 37203 (615) 254-8801 BY: MS. TRICIA HERZFELD | | Exhibit Mallinckrodt-Gillies-005 Page 80 (Dosage Suspicious Orders for Dec 2003) (MNK-T1_0001806624) |
| 16 17 | triciah@bsjfirm.com On Behalf of AmerisourceBergen: Reed Smith LLP | 15 16 17 | Exhibit Mallinckrodt-Gillies-006 Page 94 (E-mail message with attachment) (MNK-T1_0007026341 - MNK-T1_0007026342) |
| 18 19 | 136 Main Street, Suite 250 Princeton, NJ 08540 (609) 514-5959 BY: MS. SHANA E. RUSSO srusso@reedsmith.com | 18 | Exhibit Mallinckrodt-Gillies-007 (Suspicious Order Monitoring Team Charter) |
| 20 21 22 | On Behalf of Walmart: Jones Day 325 John H. McConnell Boulevard, Suite 600 | 20 | (MNK-T1 0000496062) Exhibit Mallinckrodt-Gillies-008 Page 105 (Notes from meeting with DEA Albany) (MNK-T1 0007053963 - MNK-T1 0007053966) |
| 23 | Columbus, OH 43215 (614) 469-3939 BY: MS. BRANDY H. RANJAN branjan@jonesday.com | 22 23 24 | (DEA Compliance Procedure) (MNK-T1 0000419993 - MNK-T1 0000419997) |
| | | - | |
| | Расе 3 | | Page 5 |
| 1 2 | Page 3 APPEARANCES OF COUNSEL (CONTINUED) | 1 2 | Page 5 INDEX OF EXHIBITS (CONTINUED) |
| 2 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: | 3 | _ |
| 2 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 | 2 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) |
| 2 3 4 5 6 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 | 2 3 4 5 6 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 |
| 3 4 5 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com | 2 3 4 5 6 7 8 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) |
| 2 3 4 5 6 7 8 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 | 2 3 4 5 6 7 8 9 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 Page 162 (E-mail message with attachment) |
| 2 3 4 5 6 7 8 9 10 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John | 2 3 4 5 6 7 8 9 10 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 (E-mail message with attachment) (MNK-T1_0000264240) |
| 2 3 4 5 6 7 8 9 10 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John Gillies: Ropes & Gray LLP 800 Boylston Street | 2 3 4 5 6 7 8 9 10 11 12 13 14 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 (E-mail message with attachment) (MNK-T1_0000264240) Exhibit Mallinckrodt-Gillies-015 Page 169 |
| 2 3 4 5 6 7 8 9 10 11 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CATTLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John Gillies: Ropes & Gray LLP 800 Boylston Street Boston, MA 02199 (617) 951-7000 | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 (E-mail message with attachment) (MNK-T1_0000264240) Exhibit Mallinckrodt-Gillies-015 Page 169 (11/02/10 memorandum) (MNK-T1_0000269399 - MNK-T1_0000269400) Exhibit Mallinckrodt-Gillies-016 Page 172 |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John Gillies: Ropes & Gray LLP 800 Boylston Street Boston, MA 02199 (617) 951-7000 BY: MR. ANDREW O'CONNOR andrew.o'connor@ropesgray.com MR. JOSH GOLDSTEIN | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 (E-mail message with attachment) (MNK-T1_0000264240) Exhibit Mallinckrodt-Gillies-015 Page 169 (11/02/10 memorandum) (MNK-T1_0000269399 - MNK-T1_0000269400) Exhibit Mallinckrodt-Gillies-016 Page 172 (Global Controlled Substance Compliance Procedure) (MNK-T1_0000264275 - MNK-T1_0000264278) Exhibit Mallinckrodt-Gillies-017 Page 173 |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John Gillies: Ropes & Gray LLP 800 Boylston Street Boston, MA 02199 (617) 951-7000 BY: MR. ANDREW O'CONNOR andrew.o'connor@ropesgray.com | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 Page 118 (E-mail message with attachment) (MNK-T1_0000273892 - MNK-T1_0000273895) Exhibit Mallinckrodt-Gillies-011 Page 144 (DEA Compliance Procedure) (MNK-T1_0000296382 - MNK-T1_0000296386) Exhibit Mallinckrodt-Gillies-012 Page 152 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154292 - MNK-T1_0004154296) Exhibit Mallinckrodt-Gillies-013 Page 157 (Global Controlled Substance Compliance Procedure) (MNK-T1_0004154297 - MNK-T1_0004154300) Exhibit Mallinckrodt-Gillies-014 (E-mail message with attachment) (MNK-T1_0000264240) Exhibit Mallinckrodt-Gillies-015 Page 169 (11/02/10 memorandum) (MNK-T1_0000269399 - MNK-T1_0000269400) Exhibit Mallinckrodt-Gillies-016 Page 172 (Global Controlled Substance Compliance Procedure) (MNK-T1_0000264275 - MNK-T1_0000264278) Exhibit Mallinckrodt-Gillies-017 Page 173 (E-mail chain with attachment) (MNK-T1_0000264199 - MNK-T1_0000264204) Exhibit Mallinckrodt-Gillies-018 Page 179 Page 179 |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 | APPEARANCES OF COUNSEL (CONTINUED) On Behalf of Endo Pharmaceuticals and Par Pharmaceuticals: Arnold & Porter Kaye Scholer, LLP 70 West Madison Street, Suite 4200 Chicago, IL 60602 (312) 583-2434 BY: MS. CAITLIN M. MIKA caitlin.mika@arnoldporter.com (present via speakerphone) On Behalf of Cardinal Health: Armstrong Teasdale, LLP 7700 Forsyth Boulevard, Suite 1800 St. Louis, MO 63105 (314) 552-6672 BY: MS. SARAH E. HARMON sharmon@armstrongteasdale.com On Behalf of Mallinckrodt, SpecGX LLC, and John Gillies: Ropes & Gray LLP 800 Boylston Street Boston, MA 02199 (617) 951-7000 BY: MR. ANDREW O'CONNOR andrew.o'connor@ropesgray.com MR. JOSH GOLDSTEIN joshua.goldstein@ropesgray.com | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 | INDEX OF EXHIBITS (CONTINUED) Exhibit Mallinckrodt-Gillies-010 |

| | | Page 6 | | Page 8 |
|--|---|--|--|---|
| 1 2 | INDEX OF EXHIBITS (| CONTINUED) | 1 | THE VIDEOGRAPHER: We are now on the |
| | Exhibit Mallinckrodt-Gillies-020 | Page 189 | | record. My name is James Arndt. I'm a videographer |
| 3 | (Identification and Investigation of Unusual Orders of Controlled Su | of betances | 3 | for Golkow Litigation Services. Today's date is |
| 4 | And Reports of Suspicious Order | s of | 4 | February 7th, 2019, and the time is 9:07 AM. |
| 5 | Controlled Substances) | | 5 | This video deposition is being held in St. |
| 6 | (MNK-T1_0002357607 - MNK- Exhibit Mallinckrodt-Gillies-021 | Page 192 | 6 | Louis, Missouri, in the matter of the National |
| 7 | (E-mail message with attachment (MNK-T1_0007728781 - MNK- Exhibit Mallinckrodt-Gillies-022 (Identification, Investigation, and | :) F1_0007728786) | 7 | Prescription Opiate Litigation for the United States |
| 8 | Exhibit Mallinckrodt-Gillies-022 | Page 204 | 8 | District Court for the Northern District of Ohio, |
| 9 | Reports of Controlled Substances | | 9 | Eastern Division. The deponent is John Gillies. |
| 1.0 | Suspicious Orders) | | 10 | Will counsel please identify themselves? |
| 11 | (MNK-T1_0007476261 - MNK- Exhibit Mallinckrodt-Gillies-023 | Page 211 | 11 | MR. KO: Good morning, everyone. David |
| | (Identification, Investigation, and | | 12 | Ko, Keller Rohrback, on behalf of the plaintiffs. |
| 12 | Reports of Controlled Substances Suspicious Orders) | i | 13 | MS. GAFFNEY: Alison Gaffney from Keller |
| 13 | Suspicious Orders) (MNK-T1_0005620500 - MNK- Exhibit Mallinckrodt-Gillies-024 | Γ1_0005620504) Page 214 | 14 | Rohrback on behalf of the plaintiffs. |
| | (Identification, Investigation, and | | 15 | MR. KAWAMOTO: Dean Kawamoto, also from |
| 15 | Reports of Controlled Substances | 1 | 16 | Keller Rohrback, for the plaintiffs. |
| 16 | Suspicious Orders) (MNK-T1_0000511246 - MNK-Exhibit Mallinckrodt-Gillies-025 | Γ1_0000511249) | 17 | MS. HARMON: Sarah Harmon with Armstrong |
| 1, | Exhibit Mallinckrodt-Gillies-025 (E-mail message with attachment | Page 224 | 18 | Teasdale for Cardinal Health, Inc. |
| 18 | (MNK-T1 0000263874 - MNK-T | Γ1 0000263876) | 19 | MS. HERZFELD: Tricia Herzfeld from |
| 19 | (E-mail message) | Page 254 | 20 | Branstetter, Stranch & Jennings on behalf of the |
| 20 | (MNK-T1 0003044340) | Do 20 257 | | Tennessee plaintiffs. |
| | Exhibit Mallinckrodt-Gillies-027 (Mallinckrodt Controlled Substar | Page 257 | 22 | MS. RANJAN: Brandy Ranjan from Jones Day |
| 22 | Suspicious Order Monitoring Pro (MNK-T1_0000296470 - MNK- | gram) F1_0000206476) | | on behalf of Walmart. |
| 23 | (MINK-11_0000290470 - MINK- | 11_0000290470) | 24 | MR. GOLDSTEIN: Joshua Goldstein, Ropes & |
| 24 | | | | int. Goldbildi. Vosita Goldstein, Ropes a |
| | | | | |
| | | Page 7 | | Page 9 |
| 1 | INDEX OF EXHIBITS (C | _ | 1 | Page 9 Gray, on behalf of the witness, Mallinckrodt LLC, and |
| 1 2 | | CONTINUED) | | _ |
| 2 | Exhibit Mallinckrodt-Gillies-028 | _ | | Gray, on behalf of the witness, Mallinckrodt LLC, and |
| 2 | | CONTINUED) | 2 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. |
| 3 4 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T | Page 260 1_0002077758) | 2 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf |
| 3 4 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 | Page 260 | 2 3 4 5 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. |
| 3 4 5 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) | Page 260 1_0002077758) | 2 3 4 5 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present |
| 3 4 5 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) (MNK-T1_0000284620) Exhibit Mallinckrodt-Gillies-030 | Page 260 1_0002077758) Page 262 Page 269 | 2 3 4 5 6 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present by phone please identify themselves? |
| 2 3 4 5 6 7 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) (MNK-T1_0000284620) Exhibit Mallinckrodt-Gillies-030 (Letter to Assistant U.S. Attorney) | Page 260 1_0002077758) Page 262 Page 269 | 2 3 4 5 6 7 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present by phone please identify themselves? MS. MIKA: Caitlin Mika from Arnold & |
| 2 3 4 5 6 7 8 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) (MNK-T1_0000284620) Exhibit Mallinckrodt-Gillies-030 (Letter to Assistant U.S. Attorney) (MNK-T1_0008434954 - MNK-T | Page 260 1_0002077758) Page 262 Page 269 1_0008434992) | 2 3 4 5 6 7 8 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present by phone please identify themselves? MS. MIKA: Caitlin Mika from Arnold & Porter on behalf of Endo and Par entities. |
| 2 3 4 5 6 7 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) (MNK-T1_0000284620) Exhibit Mallinckrodt-Gillies-030 (Letter to Assistant U.S. Attorney) (MNK-T1_0008434954 - MNK-T Exhibit Mallinckrodt-Gillies-031 | Page 260 1_0002077758) Page 262 Page 269 | 2 3 4 5 6 7 8 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present by phone please identify themselves? MS. MIKA: Caitlin Mika from Arnold & Porter on behalf of Endo and Par entities. MS. RUSSO: Shana Russo, Reed Smith, on |
| 2 3 4 5 6 7 8 9 | Exhibit Mallinckrodt-Gillies-028 (Draft Notes for SOM Steering Committee Meeting 09/28/11) (MNK-T1_0002077756 - MNK-T Exhibit Mallinckrodt-Gillies-029 (E-mail message) (MNK-T1_0000284620) Exhibit Mallinckrodt-Gillies-030 (Letter to Assistant U.S. Attorney) (MNK-T1_0008434954 - MNK-T Exhibit Mallinckrodt-Gillies-031 (List of files on server) (MNK-T1_0007900223) | Page 260 1_0002077758) Page 262 Page 269 1_0008434992) Page 302 | 2 3 4 5 6 7 8 9 10 | Gray, on behalf of the witness, Mallinckrodt LLC, and SpecGX LLC. MR. O'CONNOR: Andrew O'Connor on behalf of the witness, Mallinckrodt LLC, and SpecGX. THE VIDEOGRAPHER: Will attorneys present by phone please identify themselves? MS. MIKA: Caitlin Mika from Arnold & Porter on behalf of Endo and Par entities. MS. RUSSO: Shana Russo, Reed Smith, on behalf of AmerisourceBergen Drug Corporation. |
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Page 10 1 A. In St. Louis, Missouri. 1 Is that your understanding? 2 2 Q. And have you had your deposition taken A. Yes. 3 before? 3 Q. I'm going to go ahead and hand you a copy of what's going to be marked as Gillies Exhibit 1. 4 A. Yes. 5 Q. Approximately how many times? 5 [Exhibit Mallinckrodt-Gillies-001 6 6 marked for identification.] 7 Q. And was that in connection with your time Q. And I'll represent for the record that at FBI or in connection with your time at Mallinckrodt? 8 this is the amended notice of deposition pursuant to Rule 30(b)6 that we issued to Mallinckrodt. 9 With my previous employer. 10 10 Q. Not Mallinckrodt? Does that look familiar to you, Mr. 11 A. Not Mallinckrodt. 11 Gillies? 12 12 Q. So you understand generally how these A. Yes. 13 depositions go, but just as a brief reminder of the 13 Q. And just so I understand it, just so the important rules to me, it's very important that we record is clear, you are here testifying on behalf of 15 create a clean record. Mallinckrodt; is that correct? 16 As we alluded to before, the court 16 A. Correct. 17 reporter has the most important job here, so it's 17 Q. And Mallinckrodt is defined as 18 important not to speak over one another, so please wait Mallinckrodt LLC and SpecGX LLC; is that correct? 19 until I finish my question before moving on to your A. Yes. 20 response, and likewise I'll wait until you finish your 20 Q. And are you also testifying on behalf of response before moving onto my next question. Mallinckrodt PLC today? 22 22 Okay? A. No, not that I'm aware of. 23 23 A. Yes. MR. KO: And I'll note for the record, as 24 Q. It's also very important that to the counsel is aware, that Mallinckrodt PLC has moved to Page 11 Page 13 1 dismiss themselves from this litigation, but it is 1 extent that I ask a yes-or-no question and your answer 2 is in fact yes or no, please say those words rather 2 certainly plaintiffs' position that the PLC should be 3 than shaking your head or nodding your head. 3 in the litigation, and we expect this testimony to be 4 on behalf of the PLC as well. 4 Sound good? 5 A. Yes. MR. O'CONNOR: Okay. And we want to make clear that his testimony today is only on behalf of LLC 6 Q. And from time to time, counsel, your and SpecGX LLC, and PLC is not subject to the ⁷ counsel, or other counsel might object to my 8 questioning, but unless you get a clear instruction not 8 jurisdiction of the Northern District of Ohio. to answer, I'd ask that you respond to my question. BY MR. KO: 10 Does that sound good? 10 Q. Now, throughout this day -- we'll be 11 taking a look at that notice shortly, but throughout 11 A. Yes. Yes. 12 Q. And Mr. Gillies, we'll be here for a this day we'll also be looking potentially at some 13 substantial period of time today, so to the extent you documents that include Covidien e-mail addresses and Covidien labels. need breaks, please ask and we'll do our best to 15 accommodate. 15 Can we agree for purposes of the 16 16 deposition today that Mallinckrodt includes Covidien? Okay? 17 17 A. Thank you. 18 Q. Mr. Gillies, is there anything that you 18 Q. And the same with Tyco. There will be can think of today that would prevent you from 19 some -- perhaps some Tyco e-mail addresses and some testifying truthfully or honestly? Tyco documents. 21 A. No. 21 Can we agree that Tyco is synonymous with 22 Q. Great. I understand that you have been 22 Mallinckrodt for purposes of today's deposition? 23 designated on behalf of Mallinckrodt to testify on 23 MR. O'CONNOR: I just want to be very certain topics pursuant to a 30(b)6 notice. 24 clear that those are other companies, and he's

Page 14

- $^{\mbox{\scriptsize 1}}\,$ authorized to speak, as he said, on behalf of LLC and
- ² SpecGX.
- 3 MR. KO: When I refer -- I understand.
- 4 Andrew.
- 5 BY MR. KO:
- 6 Q. When I refer to Tyco and/or Covidien and
- ⁷ some documents, unless there is a clear objection or a
- 8 clear instruction otherwise, can we agree that just for
- ⁹ ease of reference that when I refer to Tyco and/or
- 10 Covidien it's also synonymous with Mallinckrodt?
- 11 A. Yes.
- Q. Okay, great. Turning to this deposition
- 13 notice. As we discussed before, there are some topics
- 14 that you have been designated to testify on behalf of
- 15 Mallinckrodt, and that includes, if you turn to Page 5,
- 16 Topic 1. Is that correct?
- 17 A. Yes.
- Q. And I also understand that you have been
- 19 designated by Mallinckrodt to testify as to portions of
- 20 Topic 2. Is that correct?
- 21 A. Yes.
- Q. And in particular I think there are some
- 23 carve-outs there, so I believe that your testimony
- 24 today is specifically regarding suspicious order

- 1 sent to you by the DEA and any other communications
- 2 between you and the DEA regarding your marketing of
- 3 your opioid products, your response to these letters,
- 4 all subsequent actions you took in response to those
- 5 communications, and all budgets for any such actions by
- 6 year, end quote.
 - Is that a correct understanding of what
- 8 you're testifying on behalf of?
- 9 A. Yes.
- Q. Great. Now, I also understand that you
- 11 are testifying on behalf of Mallinckrodt for portions
- 12 of Topic 4. Is that correct?
 - A. Yes.

13

- Q. And again, so the record is clear, the
- portion of Topic 4 that you are testifying on behalf of
- 16 Mallinckrodt today is, quote, your interactions with
- 17 the DEA regarding the scheduling of controlled
- 18 substances, the setting of quotas, or the distribution
- 19 of controlled substances, including compliance,
- 20 regulatory and administrative actions, communications,
- 21 and penalties, end quote.
- 22 Is that consistent with your understanding
- 23 that you're testifying on behalf of Mallinckrodt on
- 24 that topic?

Page 15

- 1 monitoring and potential diversion?
- 2 A. Yes.
- ³ Q. Is that correct?
- 4 A. Yes.
- ⁵ Q. And just so the record is clear, let me
- 6 read into the record the topic as I understand that you
- ⁷ are testifying on behalf of Mallinckrodt today.
- 8 And that would be, quote, the role of
- ⁹ wholesalers, distributors, and pharmacies, including
- 10 but not limited to defendants, in the supply chain for
- 11 your opioid products and the responsibilities of each
- 12 with respect to suspicious order monitoring and
- 13 potential diversion, end quote.
- Do you understand to be testifying on that
- 15 topic today?
- 16 A. Yes.
- Q. Great. Now, in addition you are also
- 18 testifying on behalf of Mallinckrodt for portions of
- 19 Topic 3; is that correct?
- 20 A. Yes.
- Q. And again, just so the record is clear,
- 22 let me read the portion of Topic 3 that I believe that
- ²³ you are testifying on behalf of Mallinckrodt.
- And that would be, quote, warning letters

- 1 A. Yes.
- Q. Great. I also understand that you are
- 3 testifying on behalf of Mallinckrodt on Topic 5. Is
- 4 that correct?
- 5 A. Yes.
- 6 Q. And in addition Topic 6?
- 7 A. Yes.
- 8 Q. Also Topic 7?
- 9 A. Yes.

14

- Q. And turning to the next page, on Page 7,
- 11 there is also Topics 14 and 15. It's my understanding
- 12 that you are testifying on behalf of Mallinckrodt on
- 3 those topics. Is that accurate?
 - A. Yes to 14. Yes to 15.
- Q. Great. And then finally if you move
- 16 forward to Page 11, I understand you are also being
- 17 designated to speak on behalf of Mallinckrodt on
- 18 portions of topic 27. Is that accurate?
- 19 A. Yes.
- Q. And again, so the record is clear, the
- 21 portion of 27 that you will be testifying on
- Mallinckrodt today is, quote, to the extent not
- 23 encompassed within other topics, your suspicious order
- 24 monitoring and compliance concerning your generic

Page 17

Page 18 1 opioid products. Is that accurate? 1 Q. Any other additional counsel? 2 2 A. Yes. A. Mr. Davison. 3 3 Q. Great. Thank you for that. Q. And approximately how many times did you MR. O'CONNOR: Counsel, just for clarity. 4 meet with them? 5 MR. KO: Sure. A. Four or five. Four in person, one 6 MR. O'CONNOR: I think on Number 4, per videoconference. Q. And when was the date of the first ⁷ our letter of October 15th, Mr. Webb was testified --8 or was designated to testify regarding all of 4 except preparation session? for the setting of quotas, and it's only the setting of A. I believe it was in September of 2018. 10 Q. And approximately how many hours would you 10 quotas that's within Mr. Gillies's topics. 11 11 say you have spent preparing for this deposition? MR. KO: And Andrew, I believe that you 12 had sent an e-mail in early January before Mr. Webb's A. Approximately 80 hours total. 13 deposition clarifying that actually Mr. Webb was only Q. And when you said a moment ago that you're 14 testifying on behalf of communications, interactions reviewing documents -- well, strike that. with the FDA. The 80 hours in preparation -- are those 16 MR. O'CONNOR: Okay. all hours you spent with counsel, or are you talking 17 about additional hours that you spent on your own MR. KO: And I had sent a follow-up e-mail 18 confirming. preparing? 19 A. No, that would be a combination of counsel 19 MR. O'CONNOR: Happy to confirm that at 20 and individual. the next break, and we can handle it --21 MR. KO: I think regardless, some of the Q. Understood. Approximately how many hours 22 questions that I'll be asking today, just for your 22 did you meet with counsel? 23 edification, that relate to the DEA could fall under 23 A. Approximately 40. 24 Q. Okay, great. And when you said a moment 24 other categories. Page 19 Page 21 1 ago you were -- that you reviewed some documents, were 1 MR. O'CONNOR: Fair enough. Thank you. 2 MR. KO: So if it becomes an issue, we can 2 these all documents that were selected by your counsel? 3 discuss and put it on the record. MR. O'CONNOR: You can answer that. 4 MR. O'CONNOR: Okay. A. Yes. 5 BY MR. KO: 5 BY MR. KO: 6 Q. Now, for the topics that we went over Q. In other words, did you provide any ⁷ today just a moment ago, again, just so the record is documents to your counsel or did you independently 8 review any documents on your own outside of counsel's 8 clear, you understand that you are speaking on behalf 9 of Mallinckrodt; correct? presence? 10 10 A. Yes. A. No. 11 Q. And you are not testifying in your 11 Q. Great. And have you reviewed any of the 12 individual capacity? court pleadings in the national opioid litigation? 13 A. So can you further define that for me? 13 A. Correct. 14 Q. And you understand that your testimony 14 Q. Sure. Have you looked at the applicable complaints in this action? will bind Mallinckrodt; is that correct? 15 15 A. Yes. A. Yes. 16 16 17 Q. Great. Mr. Gillies, what did you do to 17 O. Which ones? 18 prepare for this deposition? 18 A. The original one. 19 A. I met with counsel a number of times, 19 Q. Got it. And I'm not trying to put you through a legal test at all. 20 reviewed policies, procedures, e-mails, other 20 21 documents. 21 A. No --22 Q. And when you said counsel, is that Mr. 22 Q. I'm just trying to get an understanding of 23 O'Connor and Mr. Goldstein here? 23 what documents you may have looked at. So were these 24 24 documents also selected by counsel? A. Yes.

Page 22 Q. And Mr. Gillies, I assume that 1 A. Yes. Q. Great. In addition to complaints, were 2 ² Mallinckrodt is paying for your representation by 3 there any other pleadings or documents that looked Andrew and Joshua today. Is that correct? 4 similar to, for example, the 30(b)6 notice that's in A. Are they paying me or paying them? I'm 5 front of you that you reviewed? sorry. I don't understand the question. A. I would have looked at this document, but Q. Are you being compensated in any way for ⁷ I don't recall seeing anything else like this. your testimony today individually? 8 8 Q. Okay. Thanks. And in preparation for A. I mean, I'm employed by Mallinckrodt, so this deposition, did you speak with any current or my compensation comes from my employer. 10 former employees at Mallinckrodt? 10 Q. Outside of your regular compensation, are 11 A. Yes. you getting any additional compensation? 11 12 O. Which ones? 12 A. No. 13 A. Karen Harper. 13 Q. And are you paying for your counsel both 14 And when did you speak with her? 14 in terms of preparation for this deposition and/or 15 It would have been in January. conducting this deposition? 16 Q. January of this year? 16 A. Me personally? 17 A. I'm sorry. January 2019. 17 O. Yes. 18 Q. Great. And did you speak with her 18 A. No. 19 specifically about your deposition, or this case, or 19 Q. Great. You can set that aside. You may what did you guys discuss? want to refer to it from time to time, but I'll just --21 A. Would have discussed a question I had on we can move that aside for the moment. 22 22 one of these topics. A. Okay. 23 23 Q. Mr. Gillies, you are currently director of Q. I see. And which topic was that? 24 MR. O'CONNOR: And counsel, I'm going to 24 global security at Mallinckrodt; is that correct? Page 23 Page 25 1 object to the extent some of that discussion took place 1 A. I'm currently the vice-president of global 2 in the presence of counsel and instruct the witness not ² security. ³ to answer under attorney-client privilege. Q. Vice-president. Thanks for the MR. KO: Okay. 4 clarification. Have you ever been a director of global 5 BY MR. KO: ⁵ security or a director at Mallinckrodt? 6 Q. Do you recall -- are you going to follow A. Yes. 7 that instruction? Q. And how long -- or how long ago was that when you first became director? 8 A. Yes. 9 Q. Okay. Do you recall which topic you A. Yes. I was director when I joined 10 discussed with Ms. Harper? 10 Mallinckrodt in June of 2012. Q. And are you still currently a director or 11 MR. O'CONNOR: Same objection, same 11 12 instruction. are you no longer a director? 13 A. So I'm no longer a director. 13 BY MR. KO: Q. And when did that occur that you no longer Q. Other than Ms. Harper, did you speak with 14 any other current or former Mallinckrodt employee became a director? 16 outside the presence of counsel? A. I can't recall the exact date, but I 16 17 A. No. 17 believe it was 2015. 18 Q. And I'm sure you're aware that there are 18 Q. And so you have been vice-president of 19 other depositions taking place in this case of 19 global security since 2015? Mallinckrodt current and former employees; correct? 20 A. Correct.

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24

23 Mallinckrodt?

A. Yes.

Q. And did you review any transcripts of

21

22

24

A. Yes.

23 these depositions?

A. No.

Q. And you said a moment ago that you became

²² director in 2012. Is that also when you joined

Page 26 Page 28 Q. And approximately when in 2012? 1 1 A. No. 2 BY MR. KO: 2 June of 2012. 3 Q. Is it accurate to say that currently one Q. Well, you're familiar with the memorandum 4 of your primary responsibilities is to oversee 4 of understanding between the DEA and Mallinckrodt; 5 Mallinckrodt's compliance with the Controlled correct? Substances Act? 6 A. Yes. 7 A. I'm one of the members of the suspicious Q. And we'll get into more of the details order monitoring team. 8 later, but you're familiar with all the provisions of 8 the memorandum of understanding; is that fair? 9 Q. And in addition to being one of the 10 members of the suspicious order monitoring team, do you 10 A. Yes. 11 have additional duties to ensure that Mallinckrodt 11 Q. And in the memorandum of understanding complies with its duties under the Controlled there is a provision referenced in that agreement Substances Act? titled admission of responsibility. 14 MR. O'CONNOR: Objection to form. 14 Are you familiar with that provision? MR. O'CONNOR: Objection to form. 15 A. Yes. 15 16 BY MR. KO: 16 A. Yes. 17 17 BY MR. KO: Q. And for purposes of the deposition today, is it okay if I refer to the Controlled Substances Act 18 Q. And we can refer to the document later if as the CSA? we need to, but in that provision there's a statement 20 A. Yes. that indicates that Mallinckrodt from certain times 21 Q. And okay to refer to suspicious order through -- from 2008 to 2012 did not always comply with 22 monitoring as SOM? the standard set forth in DEA letters in 2006 and 2007 regarding its suspicious order monitoring program. 23 A. Yes. 24 24 Okay, great. And I assume that you're Isn't that accurate? Page 27 Page 29 1 familiar with the CSA; correct? MR. O'CONNOR: Objection to form. 2 A. That's my understanding without reading A. Yes. 3 Q. And you're familiar that a fundamental that document. 4 duty of any registrant of the CSA is to maintain 4 BY MR. KO: effective controls against diversion? Q. So we had just talked about one of the MR. O'CONNOR: Objection to form. duties under the CSA being a registrant's obligation to 6 7 design and implement a system to identify suspicious A. Yes. 8 BY MR. KO: 8 orders. 9 Q. And is it also fair to say that one of the Do you recall that? 10 fundamental duties of the CSA is for a registrant to 10 A. I'm sorry. Could you say that again? Sure. We had just talked about one of the 11 design and implement a system to identify and detect 11 12 suspicious orders? duties under the CSA being a registrant's obligation to 13 design and implement a system to identify suspicious MR. O'CONNOR: Objection to form. 14 A. Yes. 14 orders. 15 15 BY MR. KO: A. Yes. 16 Q. And you would certainly agree that 16 Q. And in the admission of responsibility in Mallinckrodt as a registrant of the CSA has these the MOU, memorandum of understanding, between duties; correct? 18 Mallinckrodt and DEA, Mallinckrodt acknowledged that 19 MR. O'CONNOR: Objection to form. from certain times from 2008 through 2012 it did not 20 always follow the recommendations set forth in DEA A. Yes. 21 BY MR. KO: letters in 2006 and 2007 regarding SOM programs. 22 22 Q. Now, is it accurate to state that Isn't that accurate? Mallinckrodt did not always comply with these duties? 23 MR. O'CONNOR: Objection to form. 24 MR. O'CONNOR: Objection to form. 24 A. No. No.

Page 30 1 BY MR. KO: 1 A. Until June 2012. 2 2 Q. Well, we'll get to the MOU later, then. When you went to go work for Mallinckrodt? 3 3 That's correct. Q. And both as a special agent in charge of Q. Again, I don't want this to be a memory 5 the Miami division of the FBI and even prior to that, I test or anything. want to get an understanding of when you first became Yeah. 7 aware of the opioid crisis. Q. So we'll talk about those provisions MR. O'CONNOR: Again, you can answer at a 8 later. 9 Going back to your background, I've seen general level. As we discussed, there's Touhy 10 in certain documents that you have a BA in accounting regulations that govern his ability to speak to in business from Illinois State. Is that correct? confidential information, so at a very high level you 12 A. A bachelor's of science. can answer whether you were aware. 13 A. It would have been during that time Q. Sorry. I apologize for that. A 14 bachelor's of -- so you have a bachelor's of science in 14 between 2009 and 2012. accounting and business administration from Illinois BY MR. KO: 16 State. Is that correct? 16 Q. So you -- and during that time, given that 17 you were in Florida, I presume that you became aware of That's correct. Uh-huh. 18 Q. And you graduated in 1982? certain issues with respect to the opioid crisis in 19 Florida in particular as well; correct? A. Yes. 20 And after graduation you went to work for 20 MR. O'CONNOR: Again, you can speak to the FBI, is my understanding. Is that correct? your general awareness to the extent you don't reveal 22 A. Yes. 22 any confidential government information subject to the 23 And was that immediately after graduation? 23 Touhy regulations. And if you can't answer, then I 24 24 would object and instruct you not to. No. Page 31 Page 33 Q. What did you do between graduation and A. Could you restate that question? I'm 1 working for the FBI? ² sorry about that. 3 A. I was doing accounting work, and I joined 3 BY MR. KO: 4 the FBI in October of 1983. Q. Sure, I can repeat it. 5 Q. And where did you do your accounting work? A. Yeah, could you repeat it? That's fine. 6 A. It was in Chicago. Q. Given that you were in Florida, I presume 7 Who was your employer? 7 that you became aware of certain issues with respect to 8 It was Curtis Kruber (ph) -- Kruber, CPA. the opioid crisis in Florida in particular; correct? 9 Excuse me. MR. O'CONNOR: Object to the form, and 10 Q. And when you went to work for the FBI, give the same instruction with respect to the Touhy what was your first job at the FBI? 11 issue. 12 A. It was a general support position. 12 A. I'm going to take my counsel's advice on 13 that. 13 Q. General support in what division? 14 A. Chicago division. 14 BY MR. KO: 15 Q. In what department? 15 Q. Sure. And Mr. Gillies, I'm certainly not 16 A. It was for the entire office. 16 trying to pry into anything that might be confidential 17 Q. I see. And I don't want to go over too or violate any of your obligations under the law. I'm 18 much of your background. There's -- as you understand, just trying to get a general understanding of whether 19 you have a deposition under your personal capacity or not you became aware of certain issues in Florida 20 tomorrow. But I just -- I do want to understand when related to the opioid crisis in the 2009 through 2012 21 you became a special agent in charge of the Miami 21 time period. 22 22 division. MR. O'CONNOR: Going to make the same 23 23 October of 2009. objections.

24

And how long were you in that role?

24

A. I'm going to have to take my counsel's

Page 34 1 unscrupulous doctors writing scripts for opioids as 1 advice on that. 2 BY MR. KO: 2 early as 2008? Q. Okay. Let me try this way. Mr. Gillies, MR. O'CONNOR: Objection to form. A. I don't have any recollection of it being 4 there's certainly publicly available information about 5 the role you played with respect to certain 5 2008. 6 investigations that occurred in Florida. 6 BY MR. KO: Are you aware of those? Q. I've probably seen a lot more documents 8 A. Yes. than you have. 9 Q. So I'm just asking with respect to the A. I'm sure you have. 10 publicly available information out there that suggests 10 Q. But have you in any of your review of 11 that you played a role in, for example, prosecution of 11 documents as selected by counsel today, did you see any certain pill mills in Florida, I just want to make sure reference to a growing opioid crisis and problems in 13 that the record is clear today. Florida in particular earlier than 2008? 14 14 At some point in time during the 2009 and A. No. 15 2012 time period, or perhaps before, you became aware 15 Q. And again, all these documents were 16 that there were certain issues with respect to the 16 selected by your counsel, is that correct, that you opioid crisis in Florida; is that fair? reviewed in preparation for this deposition? 18 MR. O'CONNOR: Object to form. You can 18 A. Yes. answer with respect to publicly available information. 19 Q. Mr. Gillies, you are aware of the 20 controlled substance compliance group at Mallinckrodt; A. Yes. 21 BY MR. KO: is that correct? 22 22 Q. Now, is it also accurate to say -- putting A. Yes. 23 23 aside your role in the FBI, is it also accurate to say Q. And were you ever a member or are 24 that Mallinckrodt became aware of certain issues in 24 currently a member of the controlled substance Page 35 Page 37 1 Florida as alerted by the DEA? 1 compliance group? 2 MR. O'CONNOR: Object to form.

A. I am a member of the SOM team, and we have 3 a DEA compliance group. Is that what you're referring 4 to?

Q. Well, that's actually helpful to clarify,

6 because I've seen plenty of references in the documents

7 to both a DEA compliance team and a controlled

substance compliance team.

Is it your testimony that there are two

distinct teams, or are they the same but just used

interchangeably?

12 MR. O'CONNOR: Objection to form.

13 A. So I'm sorry. I'm not familiar with that second term, the controlled substance compliance team.

I am familiar with the DEA compliance team.

BY MR. KO: 16

24

17 Q. Got it. And what are the general roles and responsibilities of the DEA compliance team?

A. I'm not part of that team, so my general 20 understanding is that that team works closing with DEA on any issues -- that's where the quota numbers are prepared from.

23 Q. In addition to quota, anything else?

A. I'm sure there are. I'm just not part of

A. Mallinckrodt became aware of the full

4 scope of the problem after a DEA meeting in August of

5 2011.

6 BY MR. KO:

7 Q. And setting aside your answer with respect

8 to the full scope of the problem, Mallinckrodt

9 understood that there were certain issues with respect

10 to the Mallinckrodt pills being diverted in Florida

11 prior to that meeting as well; correct?

12 MR. O'CONNOR: Objection to form.

13 A. Mallinckrodt was aware of an opioid

14 problem, and they were aware of unscrupulous doctors

15 writing scripts for opioids.

16 BY MR. KO:

17 Q. And what time period were they aware of

18 this?

19 A. Again, they became aware of the full scope

20 after the August 2011 DEA meeting, so they were aware

of unscrupulous doctors and some opioid issues prior to

22 that.

23 Q. And would it be accurate to say that they

24 became aware of an opioid problem and aware of

Page 38 Page 40 1 that team, so I can't give you a list. 1 compliance team? 2 2 Q. And a moment ago you said you were part of MR. O'CONNOR: Objection to form. A. I'm unaware of the SOM team being under 3 the SOM team. Is the SOM team under the umbrella of 4 the umbrella of DEA compliance. 4 the DEA compliance team, or is it a separate group? 5 BY MR. KO: 5 A. Separate. 6 Q. And currently who are the members of the Q. And is it -- so is it your test -- well, SOM team? strike that. 8 8 Did Mallinckrodt always have an A. So we have a representative from DEA compliance, from security, from legal, and government independent and separate SOM team? MR. O'CONNOR: Objection to form. 10 compliance. 11 A. So can you define always? 11 Q. And --12 There may be others. 12 BY MR. KO: 13 Q. And is the representative from security --Q. How about from the period of 2008 to the 14 is that you? period of when you joined in June of 2012, do you have 15 an understanding of whether or not the SOM team was 16 independent of any other group at Mallinckrodt? Q. And the representatives from legal -- who 17 MR. O'CONNOR: Objection to form. 17 are they? 18 MR. O'CONNOR: You can answer that. 18 A. Yes, I believe them to be independent. 19 BY MR. KO: A. Don Lohman, general counsel. 20 20 BY MR. KO: Q. Now, turning back to your testimony a 21 Q. Is he the only representative of legal on moment ago about how Mallinckrodt became aware of the 22 the SOM team? full scope of the problem in Florida after an August 23rd, 2011, meeting. 23 A. Jason Tilly. 24 Q. Is he also --Is it accurate to state that Mallin -- or Page 39 Page 41 A. Associate general counsel. 1 1 excuse me -- that the DEA focused particularly on 2 2 Mallinckrodt opioids, oxy 15s and oxy 30s in Q. And then you mentioned government 3 compliance a moment ago. Who is the individual that is 3 particular? 4 the representative on the SOM team from that group? MR. O'CONNOR: Objection to form. 5 A. Gail Tetzlaff. A. I don't know if I heard you misspeak, but Q. And have you been a member of the SOM team 6 August of 2011. Correct? 7 ever since you joined Mallinckrodt in June of 2012? BY MR. KO: A. Yes. 8 Q. Okay. I may have misspoken, and let me 9 Q. And was there ever a period of time in rephrase my question in any event to make it --10 which you were not a member of the SOM compliance team 10 A. Okay. during the time period between June 2012 and current? 11 -- hopefully a little more simple. The 12 A. I've been a member of the SOM team since I DEA met with Mallinckrodt many times during the 2009 13 joined Mallinckrodt. through 2012 time period; is that fair to say? 14 Q. So in your review of documents and in 14 MR. O'CONNOR: Objection to form. preparing for this deposition today, did you see any 15 A. I don't know about many times, but we met 16 reference to a controlled substance compliance group 16 with DEA. that was ever formed? 17 BY MR. KO: Q. Did Mallinckrodt meet with DEA on more 18 A. I have no recollection of that, but if you 18 19 have a document, I'll look at it. occasions than the August 23rd, 2011, meeting? 19 20 Q. Sure. Is it your understanding that prior 20 A. I'm sorry. Could you give me that date 21 to your employment at Mallinckrodt that the DEA 21 again? 22 compliance team was always separate from an SOM team, 22 Q. Sure. I believe that you said that the

where the SOM team was under the umbrella of the DEA

23 or was there ever a point in Mallinckrodt's history

meeting was in August of 2011.

A. That's correct.

Page 42

- 1 Q. And I believe in particular it was August
- 2 23rd of 2011.
- 3 A. Okay.
- 4 Q. That's what I --
- 5 A. That's what it was, you throwing the 23rd
- 6 at me. I'm sorry. I don't have the exact date on
- 7 that. That's why I was using August of 2011. That's
- 8 where you were throwing me off. Okay, I'm sorry. Now
- 9 I understand. Okay.
- Q. So in addition to the August 2011 meeting
- 11 with DEA, Mallinckrodt had additional meetings with DEA
- 12 regarding diversion of Mallinckrodt opioids; is that
- 13 fair to say?
- MR. O'CONNOR: Objection to form.
- 15 A. We -- Mallinckrodt had additional meetings
- 16 with the DEA. It wasn't necessarily for that purpose.
- 17 BY MR. KO:
- Q. What other purposes were they for?
- 19 A. They inspect our facilities, and so some
- 20 of the meetings were about inspections of our
- 21 facilities.
- Q. Sure. And I understand there are a
- 23 variety of purposes or a variety of reasons for why DEA
- 24 met with Mallinckrodt, but with respect to diversion of

- 1 Mall -- one of DEA's focuses were the diversion of
- 2 Mallinckrodt opioids, and in particular the diversion
- 3 of Mallinckrodt oxy 15s and 30s; is that accurate?
- 4 A. The discussion was about Mallinckrodt
- 5 oxycodone products going into Florida.
- Q. And in particular oxy 15s and oxy 30s, or
- 7 just oxycodone products in general?
 - A. 15s and 30s.
- Q. So is it fair to say that Mallinckrodt
- o knew that Mallinckrodt-manufactured opioids were being
- 1 abused and diverted in Florida?
- MR. O'CONNOR: Objection to form.
 - A. I don't know about the abuse part, but
- 14 they would have become aware of some of the diversion
- 15 of the products.
- 16 BY MR. KO:

13

- Q. And what's your understanding of
- 18 diversion, Mr. Gillies?
- A. Outside the legal supply chain. So if you
- 20 write me a legitimate script and I get it filled and I
- 21 give to it people around this table, there's diversion
- 22 there. One of the other things we could also do is we
- could have an employee that diverts product.
- Q. And could diversion lead to abuse of a

Page 43

- 1 Mallinckrodt opioids, is it your testimony today that
- 2 Mallinckrodt only met once with DEA regarding diversion
- 3 of Mallinckrodt opioids?
- 4 A. During which time frame again? I'm sorry.
- 5 Q. At any time.
- 6 A. No.
- 7 Q. So in addition to the August 2011 meeting
- 8 between Mallinckrodt and DEA, there were additional
- 9 meetings, were there not, where diversion of
- 10 Mallinckrodt opioids was discussed between Mallinckrodt
- 11 and DEA; is that fair to say?
- 12 A. Yes.
- Q. And a moment ago I had referred to oxy 15s
- 14 and oxy 30s. It's your understanding that Mallinckrodt
- 15 manufactured generic oxycodone in the 15-milligram
- 16 strength; is that accurate?
- 17 A. Yes.
- Q. And in addition, Mallinckrodt also
- 19 manufactured oxycodone 30?
- 20 A. Yes.
- Q. And for purposes of the deposition today,
- 22 is it okay if I refer to those as oxy 15s and oxy 30s?
- 23 A. Yes.
- Q. During the August 2011 meeting, one of

- 1 product?
- 2 MR. O'CONNOR: Objection to form.
- 3 A. It could.
- 4 BY MR. KO:
- 5 Q. And would you agree that diversion of an
- 6 opioid product could also lead to its misuse?
- 7 A. Could.
 - Q. Is it fair to say that Mallinckrodt was
- 9 also aware of the Oxy Express?
- MR. O'CONNOR: Objection to form.
 - A. I'm not aware of Mallinckrodt being aware
- 12 of the Oxy Express.
- 13 BY MR. KO:

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24

- Q. During both the August 2011 meetings and
- 15 other meetings, did DEA ever inform or discuss the Oxy
- 16 Express with Mallinckrodt?
- MR. O'CONNOR: Objection to form.
- A. Not that I'm aware of.
- 19 BY MR. KO:
- Q. And in your review of documents today in
- preparation for this deposition as selected by counsel,
- 22 did you see any references to the Oxy Express?
- A. I did not.
 - Q. Do you have an understanding of what the

Page 45

Page 46 Page 46

- 1 Oxy Express is?
- 2 MR. O'CONNOR: Objection. To the -- I'm
- 3 assuming, counsel, you are asking him in his capacity
- 4 as an employee of Mallinckrodt did he learn about that
- ⁵ term. Otherwise, there's Touhy implications.
- 6 So you can answer to the extent that it's
- ⁷ based on Mallinckrodt knowledge.
- 8 A. No.
- 9 BY MR. KO:
- Q. You don't have any understanding of what
- 11 the Oxy Express is?
- MR. O'CONNOR: Same --
- 13 BY MR. KO:
- Q. And I know that you keep looking at
- 15 counsel, but I'd ask that unless he actually lodges his
- 16 objection clearly on the record and instructs you not
- 17 to answer that you refrain from looking at him every
- 18 time that I ask you a question.
- A. I'm not looking at him every time you ask
- 20 me a question, but I've got legal implications when you
- 21 ask me this question, so I just want to make sure that
- 22 I'm not overstepping my legal bounds for my
- 23 responsibility to my former employer.
- So I believe I just answered your question

- A. That's my understanding.
- Q. And with respect to -- I know we had just
- 3 discussed the individuals that were part of the SOM
- 4 team. How many full-time employees are part of the SOM
- 5 team right now?
- A. Approximately nine.
 - Q. And has that changed over time?
- 8 A. It's grown.
- 9 O. And when -- when was the SOM team first
- 10 created?
- 11 A. I don't know the answer to that.
- Q. We can take a look at some documents
- 13 later, but does it refresh your recollection at all if
- 14 I say that the SOM -- it's my understanding the SOM
- 15 team was created in 2008.
- 16 Is that consistent with your
- 17 understanding, or are we going to need to look at some
- 18 more documents to establish that?
- MR. O'CONNOR: Objection to form.
- A. I don't have an understanding of exactly
- 21 when it started.
- 22 BY MR. KO:
- 23 Q. Do you have a general understanding of
- 24 whether or not it started before 2008 or after 2008?

Page 47

- 1 when it came to Mallinckrodt.
- 2 MR. O'CONNOR: I'm going to make the same
- ³ objection clearly and on the record.
- 4 BY MR. KO:
- 5 Q. So you -- have you seen any documents at
- 6 all that -- Mallinckrodt documents that reference the
- 7 Oxy Express?
- 8 A. I have not.
- 9 Q. And have you had any discussions with
- 10 anyone regarding -- outside the presence of your
- 11 counsel regarding the Oxy Express?
- 12 A. No.
- Q. So turning back to the DEA compliance
- 14 group, as it stands today, approximately how many
- 15 full-time employees are part of the DEA compliance
- 16 group?
- A. Six or seven is my estimate.
- Q. And do you have an understanding of how
- 19 that has changed over time, if at all?
- A. I don't think it's changed much over time.
- Q. So as far as you know, as far as the DEA
- 22 compliance group has been in existence, approximately
- 23 six to seven full-time employees have been part of that
- 24 group? Is that accurate?

- A. I do not.
- 2 Q. And as we discussed before with respect to

Page 49

- 3 the topics that are outlined in that notice, one of the
- 4 topics includes Mallinckrodt's suspicious order
- 5 monitoring system; is that accurate?
- 6 A. Yes.
- 7 Q. And you were -- you're prepared to testify
- 8 on behalf of the company on all things related to
- 9 suspicious order monitoring; is that fair?
- 10 A. Yes.

11

- Q. And your testimony is that you don't
- 12 know -- today you don't -- sitting here, you don't know
- 13 when the SOM team began?
 - A. That's correct. I cannot recall.
- Q. Is it -- going back to the DEA compliance
- 16 group, I know you had talked about certain things that
- 17 they were responsible for, but you couldn't recall
- 18 everything.
- 19 Is it fair to say that the DEA compliance
- 20 group is responsible for any DEA reporting requirement?
- MR. O'CONNOR: Objection to form.
- 22 A. Yes.
- 23 BY MR. KO:
- Q. And those would include any year-end ARCOS

Page 50 1 reports that Mallinckrodt has to submit to DEA; is that 1 Act. Do you recall that? 2 accurate? A. Yes. 3 Q. Now, in addition to the statute --MR. O'CONNOR: Objection to form. obviously it's complex and has many layers to it. 4 A. Yes. 5 BY MR. KO: With respect to suspicious order Q. And it would also be accurate to say that monitoring in particular, is it accurate to say that 6 the -- well, strike that. Mallinckrodt received certain letters in the 2006 and 8 The SOM team, you have testified, is 2007 time period regarding its obligations under the independent from the DEA compliance group. So I want CSA and in particular its obligations to design and implement the suspicious order monitoring system? 10 to get an understanding of whether or not the DEA 11 compliance group has any involvement in SOM whatsoever 11 MR. O'CONNOR: Objection to form. 12 or if the SOM team runs completely independent of DEA We received a DEA letter 2007 -- 2007. 12 compliance. The 2006 letter -- I don't believe we received a copy of that until later, in 2007 or 2008. 14 MR. O'CONNOR: Objection to form. BY MR. KO: 15 BY MR. KO: 15 Q. So there wasn't a question there, so I'll 16 16 Q. Okay. I'm going to go ahead and hand you just ask the question. a copy of what's been marked as Gillies Exhibit 2. 17 18 Does the DEA compliance group have any 18 [Exhibit Mallinckrodt-Gillies-002 19 responsibility over the SOM team? 19 marked for identification.] 20 A. There are DEA compliance members on the 20 Q. And for the record, Gillies Exhibit 2 is MNK-T1_000273575. And then I'm also going to hand you 21 SOM team. 2.2 Q. And which individuals are those? 22 a copy of what's going to be marked as Gillies Exhibit 23 3. 23 A. Karen Harper, Eileen Spaulding, and 24 Michelle -- and I can't recall her last name. 24 [Exhibit Mallinckrodt-Gillies-003 Page 51 Page 53 Q. Are those the only three individuals that 1 marked for identification.] 2 are both part of DEA compliance and the SOM team? O. And for the record, that ends in Bates 3 A. That's my understanding. 270069. 4 Q. And going back to the DEA compliance And let's start with the second exhibit --5 group, in addition to quota requests and communications or excuse me -- Gillies Exhibit 2. 6 with DEA regarding Mallinckrodt's quota, is it also 6 A. Okay. 7 accurate to say the DEA compliance group has Q. And I see that there's a cover letter, and 8 responsibility coordinating any audits done by DEA of 8 we can talk about that in a moment, but this is -- the Mallinckrodt facilities? letter that you see attached to this e-mail is a 10 A. Yes. 10 September 27th, 2006, letter from the DEA; is that 11 MR. O'CONNOR: Objection to form. accurate? 12 BY MR. KO: 12 A. Yes. 13 13 Q. Is it also accurate to say that the DEA O. And this -- it's signed by Joe Rannazzisi? 14 compliance group is responsible for tracking 14 Mallinckrodt's internal consumption of their quota 15 15 By the way, did you know Joe Rannazzisi request? prior to the time that you joined Mallinckrodt? 16 16 17 17 MR. O'CONNOR: Objection --A. No. 18 BY MR. KO: 18 Q. Do you know him now? 19 Q. Or of the annual quota allocation? 19 I know who he is. MR. O'CONNOR: Objection. 20 20 But you don't have a personal relationship Q. A. Yes. 21 21 with him? 22 BY MR. KO: 22 Q. Earlier we were talking about 23 Q. And in addition to the letter that you see 24 Mallinckrodt's duties under the Controlled Substances ²⁴ in -- that's reflected in Exhibit 2, there's another

Page 54

- 1 letter that's in front of you that's marked as Gillies
- ² Exhibit 3 that's dated December 27th, 2007; is that
- 3 correct?
- A. Yes.
- 5 Q. And are these the two letters that we just
- discussed a moment ago that Mallinckrodt received
- 7 regarding its duties under the CSA?
- 8 MR. O'CONNOR: Objection to form.
- 9 A. Yes.
- 10 BY MR. KO:
- 11 Q. And throughout today we might be referring
- to these letters. Is it okay if we refer to these as
- 13 the Rannazzisi letters?
- 14 A. Yes.
- 15 Q. Okay, great. So turning back to -- I'm
- 16 sorry to jump around, but turning back to Gillies
- Exhibit 2, I just want to make sure I understand your
- testimony a moment ago.
- 19 You said that you don't believe that
- 20 Mallinckrodt received this letter immediately after it
- was dated September 27th, 2006. Is that correct?
- A. That's correct. 22

A. Correct.

- 23 And your testimony is that Mallinckrodt
- 24 received it at some point in time in 2007 or 2008?

- 1 I'm familiar with Eldon's name, but not ² Todd.
- 3 And who is Eldon Henson, and what was his
- A. I'm sorry. I don't know what his role
- 6 was.
- Q. Okay. Fair enough. And there are also
- 8 references, if you look on Pages 2 and 3 of this
- e-mail, to Vince Kaiman and Tim Wright.
- Do you know who those individuals are?
- A. I do not. 11

4 role at Mallinckrodt?

- 12 Q. Now, if you look at the second page of
- 13 this e-mail. Sorry, just stick on that exhibit.
- 14 A. This one? Okay.
- 15 Q. Yeah. Thank you. So the second page of
- that e-mail -- I'm about two-thirds of the way down --
- there is an e-mail from Dirk Stevens to Eldon Hanson.
- Do you see that?
- 19 A. Yes.
- 2.0 Q. From December 13th?
- 21 A. Yes.
- 22 Q. 10:45? And again, Eldon Hanson was a
- 23 Mallinckrodt employee; is that correct?
- A. Yes.

Page 55

Q. And in that e-mail, he is being asked by

Page 57

- 2 Dirk Stevens, quote, do you have a diversion policy.
- 3 Do you see that?
- A. Yes.
- What is your understanding -- well, strike
- 6 that.
- With respect to Mallinckrodt's obligations
- 8 under the CSA, and in particular its obligations to
- design and implement an SOM program, when did
- Mallinckrodt first memorialize in writing a policy with
- respect to these obligations?
- 12 MR. O'CONNOR: Object to form.
- 13 A. So Mallinckrodt always had an SOM program,
- but I do not know the date of any formal document.
- BY MR. KO:
- Q. When you say that Mallinckrodt always had 16
- an SOM program, can you -- do you have an understanding
- of when it first began?
- 19 A. I do not.
 - Q. And do you have -- I assume I know the
- answer to this, but when Mallinckrodt first implemented
- 22 an SOM program, do you know if there was any policy
- 23 memorialized in writing regarding that program at that
- 24 time?

20

- Q. And I just want to clarify for the record.
- 3 If you look at the cover e-mail, you see Ms. Harper
- 4 sending this letter around. Is that accurate?
- 5 MR. O'CONNOR: Objection to form. 6 A. So this is from Karen, and the attachment
- ⁷ says DEA letter September 27th, 2006.
- 8 BY MR. KO:

- 9 Q. So I just want to clarify for the record.
- 10 I want to make sure that it's clear.
- 11 Is it accurate to say that Mallinckrodt
- received or individuals at Mallinckrodt received this
- 13 letter in 2007?
- 14 A. The date of this is December 13th, 2007.
- 15 Q. So yes or no? Is it accurate to say that
- 16 Mallinckrodt received the September 27th, 2006,
- Rannazzisi letter at some point in 2007?
- 18 A. Yes.
- 19 Q. And by the way, there are some individuals
- 20 that are referenced in this letter at Mallinckrodt,
- 21 including individuals by the name of Eldon Hanson and
- 22 Todd Forthaus. Do you see that?
- 23 A. Yes.
- 24 Do you know who they are?

Page 58 Page 60 1 A. I do not. 1 Mallinckrodt? 2 2 Q. And turning to the top of the first page, A. No. 3 the Karen Harper e-mail to Bill Ratliff. There's an O. Do you know whether or not -- I -- well, 4 occasion -- do you see -- about three lines down where 4 strike that. 5 she indicates that, quote, she was forwarded policy E-9 Turning to this letter, there are a series for St. Louis and A-14 for WGTC regarding the same. of statements being made with respect to a registrant's duties around the CSA. Is that accurate? Okay. 8 A. Yes. 8 And for ease of reference, you can see Q. Q. And in the second paragraph, there is a 9 the --10 statement made by DEA that, quote, in addition to and A. Okay. Q. Obviously the exhibit is in front of you, not in lieu of the general requirement under 21 U.S.C. 11 but if you'd like to look at the big screen, it's there 823 that manufacturers and distributors maintain 13 behind me as well. 13 effective controls against diversion, DEA regulations 14 Do you have any understanding of what the require all manufacturers and distributors to report suspicious orders of controlled substances, Title 21 15 security policy E-9 is? CFR, 1301.74B. 16 A. I do not. 17 17 Q. Or do you have any understanding of what Did I read that portion correctly? 18 the A-14 for WGTC is? 18 A. That's what this letter states. 19 19 A. I do not. Q. And so is it accurate to say that 20 Mallinckrodt knew that the obligation to report Q. Is there any indication in that e-mail 21 that Karen Harper is actually providing anyone with the suspicious orders of controlled substances was an 22 diversion policy requested in the previous e-mail we additional requirement under the CSA as required by the 23 looked at? 23 CFRs? 24 24 A. Could you say that again? MR. O'CONNOR: Objection to form. Page 59 Page 61 A. Yes. 1 Q. Let me ask it a different way. Do you ² have any understanding whether Mallinckrodt as of 2 BY MR. KO: ³ December 2007 had a written SOM policy? Q. And moving on to the second part of that A. I'm unaware whether they did or did not. 4 sentence. The letter continues, quote -- well, strike You can set that aside and look at Gillies 5 that. Q. 6 Exhibit 3. The letter indicates that DEA regulations, 7 quote, require that a registrant design and operate a And so this is the second Rannazzisi system to disclose to the registrant suspicious orders 8 letter that Mallinckrodt received from DEA; is that 9 of controlled substances, end quote. correct? 10 A. Yes. 10 Did I read that correct -- portion of the 11 Q. And there's a received stamp that paragraph correctly? indicates that Mallinckrodt in fact received this at 12 A. Yes. 13 13 least no later than January 4th, 2008. Is that Q. And so in addition to the duty to maintain ¹⁴ accurate? effective controls against diversion, Mallinckrodt knew 15 that it had to design and operate a system to disclose A. Yes. to the registrant suspicious orders of controlled 16 Q. And this particular letter is specifically addressed to Mallinckrodt Hobart facility? substances; is that accurate? 18 18 A. Yes. A. Yes. 19 Q. And so the record is clear, there's no 19 Q. And moving on to the next sentence, it ²⁰ dispute that Mallinckrodt received this letter; indicates that the regulation -- let me be clear. 21 correct? 21 The next statement states, quote, the 22 22 regulation clearly indicates that it is the sole

Q. By the way, do you have an understanding

²⁴ of who these Rannazzisi letters were circulated to at

23

23 responsibility of the registrant to design and operate

24 such a system, end quote.

Page 62 1 Did I read that correctly? 1 prior to completing a sale to determine whether the 2 A. Yes. ² controlled substances are likely to be diverted from 3 Q. And so is it fair to say that Mallinckrodt ³ legitimate channels. 4 knew as of the date of receiving this letter that the Did I read that correctly? 5 DEA expected the sole responsibility to design and A. Yes. operate an SOM system to lie with the registrant -- in Q. So again, is it fair to say that the DEA this case, Mallinckrodt? expectation as of the date of this letter was that --8 MR. O'CONNOR: Objection to form. and Mallinckrodt in fact understood that their BY MR. KO: responsibilities do not end with merely filing a 10 Q. Is that correct? suspicious order report? Is that accurate? 11 A. Yes. 11 MR. O'CONNOR: Objection to form. 12 12 Q. Now, moving on to the third paragraph. Yes. Α. 13 The second sentence indicates, quote, filing a monthly 13 BY MR. KO: 14 report of completed transactions, for example, Q. In other words, Mallinckrodt must, as of 15 excessive purchase report or high unit purchases, does the date of this letter, conduct an independent 16 not meet the regulatory requirement to report analysis of suspicious orders prior to completing a suspicious orders, end quote. sale determine -- to determine whether the controlled 18 Did I read that correctly? substances are likely to be diverted. Is that 19 A. That's what it says. accurate? 20 20 Q. So is it fair to say that Mallinckrodt MR. O'CONNOR: Objection. 21 understood that simply filing a monthly excessive order 21 A. Yes. 22 report would not meet the regulatory requirements under 22 BY MR. KO: 23 the CSA? 23 O. So as of the date of this letter, it would 24 24 be accurate to say that if Mallinckrodt released an MR. O'CONNOR: Objection to form. Page 63 Page 65 A. When this letter received, that was the 1 order prior to completing a sale and without doing any 1 2 industry standard prior. ² sort of independent analysis would not be consistent 3 BY MR. KO: with the standard set forth in this letter? 4 Q. And I understand, but my question was just MR. O'CONNOR: Objection to form. simply a yes-or-no question. A. I'm sorry. Could you state that one more Is it fair to say that Mallinckrodt 6 6 time? 7 understood that simply filing a monthly excessive order 7 BY MR. KO: 8 report would not meet the regulatory requirements under Q. Sure. Would it be accurate to say that if the CSA as of the date of this letter? Mallinckrodt released an order prior to completing a 10 MR. O'CONNOR: Objection to form. sale and without doing any sort of independent 11 A. Yes. 11 analysis, that would not be consistent with the 12 BY MR. KO: standard set forth in this letter? 13 13 Q. So if Mallinckrodt was sending monthly A. No. 14 reports to DEA after January 4th, 2008, that would not 14 MR. O'CONNOR: Same objection. be consistent with the standard set forth in this 15 BY MR. KO: letter; is that accurate? 16 Q. It would not be accurate to say that? 16 17 MR. O'CONNOR: Objection to form. 17 A. Correct. 18 A. Yes. 18 Q. And why is that? 19 BY MR. KO: 19 This is referring to suspicious orders. 20 Q. Going on to the next sentence, the letter 20 I see. I see what you're saying. Let me indicates, that quote, registrants are reminded that 21 rephrase my question. 22 their responsibility does not end merely with the 22 So would it be accurate to say -- well, 23 filing of a suspicious order report. Registrants must 23 strike that. conduct an independent analysis of suspicious orders 24 In the third sentence that we just read,

Page 66

- 1 the DEA provides guidance, does it not, that
- ² registrants must conduct an independent analysis of
- 3 suspicious orders prior to completing a sale?
- 4 A. Yes.
- 5 Q. So are you suggesting that that provision
- 6 only applies with respect to a suspicious order but not
- ⁷ any other order?
- 8 A. Yes, that's what the regulation says.
- 9 Q. And what is your understanding of what
- 10 constitutes a suspicious order?
- 11 A. So DEA defines it as size, normal
- 12 pattern -- and there's a third one. Yeah.
- Q. Well, it's actually -- it's later on in
- 14 this letter, so why don't we actually turn to that
- ¹⁵ portion of this letter.
- The fourth paragraph down at the bottom of
- 17 this page states the regulation specifically states
- 18 that suspicious orders include orders of an unusual
- 19 size, orders deviating substantially from a normal
- pattern, and orders of an unusual frequency, end quote.
- pattern, and orders of an unusual frequency, end q
- 21 Did I read that correctly?
- 22 A. Yes.
- Q. So is it your understanding that a
- 24 suspicious order, among other things, constitutes those

- 1 quantities of one particular controlled substance
- ² relative to others it orders?
- 3 MR. O'CONNOR: Objection to form.
- 4 A. So could you further define that?
- 5 BY MR. KO:
- 6 Q. Well, is one purpose -- well, would you
- agree with me that a pharmacy that orders 90 percent --
- 8 for example, 90 percent of one particular drug relative
- 9 to others would warrant further investigation?
- 0 MR. O'CONNOR: Objection --
- A. So I'm not going to see that as the
- 12 manufacturer.
- 13 BY MR. KO:
- Q. What do you mean by that?
- A. I'm not selling to pharmacies. We sell to
- 16 the distributors and wholesalers who sell to the
- 17 pharmacies. So I'm not going to see any other product,
- 18 and we're only selling the generic controlleds to the
- 19 distributors and wholesalers.
- Q. At a certain point in time Mallinckrodt
- 21 became aware and had access to information regarding
- 22 downstream transactions between its wholesale
- 23 distributor customers and pharmacies and clinics; is
- 24 that accurate?

Page 67

- 1 elements?
- 2 A. Yes.
- Q. And so would it be accurate to say that
- 4 one purpose of why Mallinckrodt designed and
- 5 implemented a suspicious order monitoring system is to
- 6 identify orders of an unusual size?
- 7 A. Yes.
- 8 Q. And also to identify orders that deviate
- 9 substantially from a normal pattern?
- 10 A. Yes.
- Q. And also Mallinckrodt designed and
- 12 implemented an SOM program to identify orders of an
- 13 unusual frequency?
- 14 A. Yes.
- Q. Would you agree with me that one of the
- 16 purposes of identifying a suspicious order is also to
- 17 make sure that Mallinckrodt fills orders only for
- 18 legitimate scientific and medical means?
- MR. O'CONNOR: Objection to form.
- 20 A. Yes.
- 21 BY MR. KO:
- Q. Now, is it also fair to say that an
- 23 effective SOM program would also be able to identify
- 24 whether a pharmacy or clinic is ordering excessive

- Page 69
- A. With pharmacies. Not all pharmacies.
- 2 Some pharmacies.
- Q. So yes or no? At a certain point in time,
- 4 Mallinckrodt became aware and had access to information
- 5 regarding downstream transactions between its wholesale
- 6 distributor customers and pharmacy and clinics; is that
- 7 accurate?
- 8 MR. O'CONNOR: Objection to form.
- 9 A. Could you restate that question or at
- 10 least just repeat it one more time?
- 11 BY MR. KO:
- Q. Sure. At a certain point in time,
- 13 Mallinckrodt became aware and had access to information
- 14 regarding downstream transactions between its wholesale
- 15 distributor customers and pharmacies and clinics?
- MR. O'CONNOR: Same objection.
- 17 BY MR. KO:

- Q. Is that accurate?
- 19 A. For some of them, yes.
- Q. And I know that you just said a moment ago
- 21 that Mallinckrodt had no visibility beyond -- or I
- 22 don't -- I'm not trying to take words out of your
- 23 mouth, but you seemed to imply that Mallinckrodt did
- 24 not know what was going on with respect to its drugs

Page 70 1 after it went to the distributor. 1 that's going to depend on what my answer is. 2 That's not entirely accurate; is that ² BY MR. KO: 3 correct? Q. Okay. Let's start with the manufacturers. MR. O'CONNOR: Objection to form. A. No. 5 A. That wasn't your question, so that was not O. Your answer is no? 6 my response. That's a completely different thing that 6 A. Yes. ⁷ you're asking me now. Q. Let's turn to the top of Page 2. 8 8 BY MR. KO: Actually, before we get there, I also want Q. Okay. So I'll go back to my original to ask whether or not you would agree with me that an 10 question, then. 10 effective SOM program would also be able to identify 11 11 whether or not a pharmacy or clinic is ordering from A. Okay. 12 multiple distributors with respect to the same Q. Wouldn't it be reflective -- well, strike 13 that. controlled substance. 14 Would you agree with me that an effective 14 MR. O'CONNOR: Objection to form. 15 suspicious order monitoring program would be able to 15 That would be a factor to consider. 16 identify whether a pharmacy or clinic is ordering 16 BY MR. KO: excessive quantities of a limited variety of controlled 17 Q. And in addition to a factor to consider, substances? would it be reflective of an effective SOM program for 19 MR. O'CONNOR: Objection to form. a registrant to determine whether or not a pharmacy or 20 A. I'm not going to see, as the manufacturer, clinic is ordering the same controlled substance from 21 all the products that they are or are not ordering. multiple distributors? 22 22 BY MR. KO: MR. O'CONNOR: Objection to form. 23 23 Q. Yeah. Regardless of whether or not you A. It would be a factor to consider. 24 can see, and we can talk -- discuss later about all the 24 BY MR. KO: Page 71 Page 73 1 pieces of information that a registrant potentially 1 Q. And I'm asking a yes-or-no question. 2 could have had -- any particular manufacturing 2 A. Oh, I'm sorry. 3 registrant. Q. Yeah. Yes or no, would it be reflective But for purposes of an SOM program -- you 4 of an effective SOM program for a registrant to 5 have responsibilities with respect to the SOM program 5 determine whether or not a pharmacy or clinic is 6 today, do you not? 6 ordering the same controlled substance from multiple 7 A. Yes. distributors? 8 Q. And I'm simply asking whether or not you MR. O'CONNOR: Objection to form. 9 believe -- or you would agree with me that an effective A. Yes. 10 SOM program would be able to identify, regardless of 10 MR. O'CONNOR: Counsel, we're about an 11 hour and 20 minutes in. Can we take a five- or 11 whether or not you think the manufacturer can or cannot 12 identify the details of the downstream transaction --10-minute break? 13 would you agree that an effective SOM program would be 13 MR. KO: Sure. Sounds good. 14 14 able to identify whether a pharmacy or clinic is MR. O'CONNOR: Okay. ordering excessive quantities of a limited variety of 15 THE VIDEOGRAPHER: We are going off the controlled substances? 16 record at 10:22 AM. 16 17 17 MR. O'CONNOR: Objection to form. [A brief recess was taken.] 18 A. Are you talking about my SOM program? 18 THE VIDEOGRAPHER: We are back on the 19 BY MR. KO: record at 10:40 AM. 20 Q. I'm talking about an effective SOM --20 BY MR. KO: 21 Q. Welcome back from the break. Just a few 21 program. 22 22 more questions on Exhibit 3. You have it in front of 23 MR. O'CONNOR: Same objection. 23 you.

24

A. Manufacturers or distributors? I mean,

24

At the top of Page 2, there's a statement

Page 74

- 1 that says, quote, registrants that rely on rigid
- 2 formulas to define whether an order is suspicious may
- 3 be failing to detect suspicious orders. For example, a
- 4 system that identifies orders as suspicious only if the
- 5 total amount of controlled substance ordered during one
- 6 month exceeds the amount ordered the previous month by
- ⁷ a certain percentage or more is insufficient.
- 8 Did I read that correctly?
- 9 A. Yes.
- Q. So would you agree with me that
- 11 Mallinckrodt knew as of the date of this letter that
- 12 rigid -- adherence to a rigid formula to define whether
- 13 an order is suspicious would be inadequate?
- MR. O'CONNOR: Objection to form.
- 15 A. That's what the letter says, yes.
- 16 BY MR. KO:
- Q. So yes or no? Would you agree with me
- 18 that Mallinckrodt knew as of the date of this letter
- 19 that adherence to a rigid formula to identify whether
- an order is suspicious would be inadequate?
- 21 MR. O'CONNOR: Objection to form. Asked
- 22 and answered.
- 23 A. Yes.
- 24 BY MR. KO:

- Page 75
- 1 Q. Thank you. Now, we had discussed -- you
- ² can set this aside, actually.
- 3 A. Okay.
- 4 Q. Earlier we had discussed whether or not
- ⁵ Mallinckrodt had written policies with respect to its
- 6 SOM program.
- 7 Do you recall that testimony?
- 8 A. Yes.
- 9 Q. And I know you said you don't recall when
- 10 it first started, but at a certain point in time there
- 11 were certain written policies that were drafted and
- 12 revised and circulated within Mallinckrodt; is that
- 13 correct?
- 14 A. Yes.
- Q. And when do you recall the first written
- ¹⁶ policy -- or when did Mallinckrodt first begin writing
- 17 or drafting these written policies?
- MR. O'CONNOR: Objection to form.
- A. I don't have any recollection of the date.
- 20 BY MR. KO:
- Q. And you understand -- Mallinckrodt -- is
- 22 it accurate to say that Mallinckrodt manufactured
- ²³ opioids beginning in approximately 1996?
- MR. O'CONNOR: Objection to form.

- Page 76
- A. I believe we were manufacturing opioids at
- 2 least from 1996.
- 3 BY MR. KO:
 - Q. And did Mallinckrodt have an SOM program
- 5 since when it began manufacturing prescription opioids?
- A. That's my understanding.
 - Q. But you don't have a recollection of
- 8 whether or not there was a written policy at the time
- 9 that first -- that Mallinckrodt first began
- manufacturing prescription opioids; is that accurate?
- 11 A. That's correct.
- Q. Now, with respect to the suspicious order
- 13 monitoring procedures, is it accurate to state that
- 14 Mallinckrodt had at certain points a two-tiered system
- 15 to identify suspicious orders?
- MR. O'CONNOR: Objection to form.
- 17 A. Yes.
- 18 BY MR. KO:
- Q. And I understand and I believe that there
- 20 are three tiers now, but for some portion of when
- 21 Mallinckrodt had an SOM program, there were two tiers
- 22 with respect to identifying a suspicious order; is that
- 23 correct?
- 24 MR. O'CONNOR: Objection to form.
- Page 77
- 1 A. So I believe there's two tiers now.
 - ² BY MR. KO:
 - Q. Oh, is that -- okay. Was there ever a
 - 4 time that there was a three-tier system?
 - 5 A. Yes.
 - 6 Q. And with respect to the two-tiered system,
 - ⁷ the first tier -- and correct me if I'm wrong -- but
 - 8 the first tier attempts to identify whether an order is
 - o the first tier attempts to identify whether an order is
 - ⁹ either peculiar or unusual; is that accurate?
- MR. O'CONNOR: Objection to form.
- 11 A. The Tier 1 of the program applies to the
- big three plus one regarding oxy 15s and oxy 30s.
- 13 BY MR. KO:
- Q. And that's the two-tier structure right
- 15 now that you're describing; correct?
- 16 A. That's correct.
 - O. Let's talk about the 2008 to 2012 time
- 18 period.

- 19 A. Okay
- Q. Did you have an understanding of whether
- 21 or not there were two or three tiers during that time
- 22 period?
- 23 A. In --
- MR. O'CONNOR: Objection to form.

Page 78 1 A. In early 2012, there was the three-tiered 1 Q. And you have -- in addition to not knowing 2 system. ² exactly how many, you don't have any understanding of 3 the general amount of suspicious orders that were 3 BY MR. KO:

- 5 And then September 2012 was a two-tiered
- 6 system.
- 7 Q. Got it. Thank you. And so prior to 2012,
- 8 was the SOM program -- the intent of the SOM program
- was to have a two-tiered system?

Q. And so prior to --

- 10 MR. O'CONNOR: Objection to form.
- A. I don't know what that intent was. 11
- 12 BY MR. KO:
- 13 Q. Sure. Well, I was hoping not to go
- 14 through each -- well, we will go through some of the
- 15 SOM policies, but I'm just hoping to get a general
- 16 understanding of what your -- of the systems that
- 17 Mallinckrodt had in place, but we can look at the
- policies in a moment.
- 19 A. Okay.
- 20 Q. Now, do you have an understanding of how
- 21 many orders Mallinckrodt has identified as being
- 22 suspicious?
- 23 A. I do not.
- 24 Q. You have no understanding of how many

- A. I don't. I just know that there were
- suspicious orders reported to the DEA.

4 reported to the DEA prior to 2008?

- Q. From the period 2008 through 2011, do you
- 8 have any understanding of how many suspicious orders
- were reported to the DEA?
- 10 A. I do not.
- 11 Q. I'm going to hand you a copy of what will
- be marked as Gillies Exhibit 4 and --
- MS. GAFFNEY: 5.
- 14 BY MR. KO:
- 15 -- 5. And for the record I'll note that
- Gillies Exhibit 4 ends in Bates 1806623, and Exhibit 5
- is actually the attachment which ends in 1806624.
- 18 [Exhibit Mallinckrodt-Gillies-004
- 19 marked for identification.]
- 20 [Exhibit Mallinckrodt-Gillies-005
- 21 marked for identification.]
- 22 Q. So Mr. Gillies, does this document look
- 23 familiar to you at all?
- 24 A. I mean, I don't recall it, but --

Page 79

- 1 orders Mallinckrodt has notified to the DEA at any
- point in Mallinckrodt's history as to how many orders
- 3 are suspicious?
- A. I know there has been suspicious orders,
- 5 and I know they've been identified to the DEA.
- 6 Q. But you have no understanding of how many
- ⁷ orders have been identified to the DEA?
- 8 A. I do not.
- 9 Q. As you know, other depo -- other
- 10 individuals have been deposed in this case, and Ms.
- 11 Harper has testified that prior to 2008, Mallinckrodt
- had identified approximately 10 or less suspicious
- 13 orders to the DEA.
- 14 Does that sound familiar to you at all?
- MR. O'CONNOR: Objection to form. 15
- 16 A. It does not, but --
- 17 BY MR. KO:
- 18 Q. Does it refresh your recollection at all
- 19 that Mallinckrodt had identified only a small number of
- suspicious orders prior to 2008?
- 21 MR. O'CONNOR: Objection to form.
- 22 A. Again, I don't know how many there were
- 23 prior to that time.
- 24 BY MR. KO:

- Q. Well, let's just take a look at the
- ² first -- well, this -- for the record, this is an
- ³ e-mail that Karen Harper sends to you on April 25th,

Page 81

- 4 2014. Is that accurate?
- A. Yes.
- Q. And at the top of the e-mail she states,
- quote, 12-31-2003, the oldest SOM report to DEA that
- 8 was retrievable this evening attached. Given the
- report number identity, we may be able to retrieve
- older information through IS, end quote.
- 11 Did I read that correctly?
- 12 A. Yes.
- 13 Q. First off, IS is information systems;
- 14 correct?

- 15 A. Yes.
- 16 Q. And that's a group at Mallinckrodt; right?
- 18 Q. And they were -- they had some
- responsibilities with respect to the SOM program? 19
- 20 MR. O'CONNOR: Objection to form.
- 21 BY MR. KO:
- 22 Q. Is that accurate?
- 23 A. I don't know what their role would have
- 24 been. This is our IT department, and so I don't know

Case: 1:17-md-02804-DAP Doc#: 3013-11 Filed: 12/18/19 23 of 85 PageID #: 446014 Further Confidential ty Review Page 82 Page 84 1 peculiar? ¹ if they were just pulling records for her. 2 Q. Sure. So that's helpful. So the IS group A. Yes. ³ referenced here is essentially the IT department at Q. And if that algorithm was triggered, a 4 report was created? Is that accurate? 4 Mallinckrodt; correct? 5 A. Yes. A. That's correct. Yeah. Q. And does the IT department currently have Q. And the reports that are referenced here 7 in this e-mail that were temporarily discontinued to be ⁷ a role with respect to retrieving information for purposes of Mallinckrodt's SOM program? 8 sent to the DEA, those are those peculiar order A. Yes. reports; is that accurate? 10 Q. And they provide regular monthly reports A. That's my understanding. 11 to the SOM team; is that accurate? 11 Q. And the e-mail goes on to state that the 12 12 SOM team is working on a revised algorithm system, and MR. O'CONNOR: Objection to form. 13 A. I don't know how regularly they provide 13 that -- well, first of all, you see that portion of the 14 that information. 14 e-mail? 15 15 BY MR. KO: A. Yes. 16 16 Q. And the revised algorithm system is with Q. Now, this document indicates that the 17 respect to the peculiar order algorithm; is that earliest SOM report, at least as of 2014, that Ms. Harper could find was from 2003. Is that accurate? accurate? 19 19 A. Yes.

20

23

24

A. That's what it says. And it says we may be able to retrieve older information through the IT 21 department.

22 Q. And have you seen any suspicious order reports prior to 2003?

24 A. Not that I can recall.

order; is that accurate?

A. Yes.

Page 83 Q. Are you aware of any suspicious order ² reports prior to 2003?

3 A. No.

4 Q. Now, in the next sentence down, Ms. Harper 5 indicates to you, quote, 10-2008. SOM report 6 submission to DEA local office is temporarily ⁷ discontinued per direction of DEA. SOM team begins 8 work on revised algorithm system.

9 Did I read that correctly?

10 A. Yes.

11 Q. And what is your understanding of which 12 reports were being discontinued per the direction of

13 the DEA?

A. The peculiar order reports.

15 Q. And is it accurate to say that those are 16 the monthly reports that -- well, let's take a step

17 back.

14

18 What are the peculiar order reports that 19 Mallinckrodt created prior to October of 2008?

A. So they would have been the algorithm 21 reports to show any orders regarding the unusual size, 22 pattern, et cetera.

23 Q. So is it fair to say that Mallinckrodt had 24 an algorithm to determine whether or not an order was 1 the time of this e-mail and as of the time that

Q. And to be clear, Mallinckrodt

distinguished between a peculiar order and a suspicious

Page 85

Q. And the basic structure, at least as of

² Mallinckrodt utilized peculiar orders -- the basic

3 structure was if an order was determined to be

4 peculiar, it would be elevated for further review to

5 determine whether or not it was suspicious for purposes

6 of notifying the DEA; is that accurate?

A. Correct.

Q. And so when this e-mail is discussing --

when Ms. Harper is discussing with you the fact that

10 these reports are being temporarily discontinued per

11 the direction of the DEA, what is your understanding of

what Ms. Harper is referring to here?

13 MR. O'CONNOR: Objection to form.

A. She's referring to the reports that we

were sending to the DEA are no longer being sent to the

16 DEA per their direction.

BY MR. KO: 17

14

24

18 Q. And was -- and I guess I was unclear, and

19 I apologize for that. The direction of the DEA -- I

want to focus on that portion.

21 Is that in reference to the Rannazzisi 22 letters that we were just discussing a moment ago?

23 A. Yes. The December 2007 letter.

Q. Correct. And the portion of that letter

Page 86

- 1 that discusses the concept of not sending monthly
- 2 excessive order reports to DEA; correct?
- 3 A. That's right. That was the industry
- 4 standard, and then in that letter they said
- 5 discontinue.
- 6 Q. And that letter, to be clear, was dated
- 7 December 27th and received in January of 2008; correct?
- 8 A. That's the date stamp on here, yes.
- 9 Q. And this chronology indicates that
- 10 Mallinckrodt stopped sending the reports in October of
- 11 2008; correct?
- A. That's what this indicates, but that's not
- 13 what my recollection is, that we had stopped submitting
- 14 these reports a lot earlier than this.
- Q. So would it be accurate to say that if
- 16 Mallinckrodt sent monthly reports at some point in time
- between January of 2008 and October of 2008, that would
- 18 be inconsistent with the standard set forth in the
- 19 December 27th, 2007, Rannazzisi letter; correct?
- MR. O'CONNOR: Objection to form.
- A. Per the December 2007 letter, the DEA was
- 22 advising registrants to stop sending those reports.
- 23 BY MR. KO:
- Q. So would it be accurate to say that if

- Q. Now, further on in this e-mail, the next
- ² section down, Ms. Harper indicates 7-20-2010, DEA St.
- 3 Louis visits St. Louis plant for a physical security
- 4 inspection, and advises Mallinckrodt that DEA SOM
- 5 expectation is that Mallinckrodt know their customer's
- 6 customer.
- 7 Did I read that correctly?
- 8 A. Yes.
- 9 Q. So is it accurate to say that Mallinckrodt
- 10 knew at least as of July 20th, 2010, that the DEA
- 11 expected Mallinckrodt to know their customer's
- 12 customer?
- MR. O'CONNOR: Objection to form.
- A. So it's not part of the regulations, but
- 15 that's what DEA was advising us now, that they expected
- 16 us to know our customer's customer.
- 17 BY MR. KO:
- Q. So is it accurate to say that as of July
- 19 20th, 2010, Mallinckrodt knew that the DEA expected
- 20 Mallinckrodt to know their customer's customer?
- 21 MR. O'CONNOR: Objection to form.
 - A. That's what the DEA in St. Louis advised
- 23 us.

22

24 BY MR. KO:

Page 87

- 1 Mallinckrodt sent monthly letters to DEA between
- ² January 2008 and October 2008, that practice would be
- ³ inconsistent with the standard set forth in the
- 4 December 27th, 2007, Rannazzisi letter; correct?
- 5 MR. O'CONNOR: Objection to form.
- 6 A. So to be accurate, those SOM reports. I
- ⁷ believe you used the term letter, so I just want to
- 8 make sure that it was -- I don't want to be confused.
- 9 So I think you're talking about the
- 10 reports; correct?
- 11 BY MR. KO:
- 12 Q. Sure. So --
- 13 A. Okay.
- Q. And you're absolutely right. Thank you
- 15 for the clarification. So just so the record is
- 16 perfectly clear, would it be fair to say that if
- 17 Mallinckrodt sent monthly reports to the DEA between
- 18 January 2008 and October 2008 regarding any kind of
- 19 excessive order, that practice would be inconsistent
- with the standard set forth in the December 27th, 2007,
- 21 Rannazzisi letter; correct?
- MR. O'CONNOR: Same objection.
- 23 A. Yes.
- 24 BY MR. KO:

Q. And further on in that paragraph, there's

Page 89

- 2 also an indication that Mallinckrodt begins evaluating
- 3 the use of chargeback data for SOM. Do you see that
- 4 portion of the e-mail?
- 5 A. Yes.
- 6 Q. And so at least as of July 2010,
- 7 Mallinckrodt -- is it fair to say that Mallinckrodt
- 8 began contemplating use of chargeback data in
- 9 connection with its suspicious order monitoring
- 10 program?
- 11 A. Yes.
- Q. And turning to the -- actually, turning to
- 13 the attachment of the e-mail, which as indicated by Ms.
- 14 Harper's cover e-mail to you was an SOM report. Do you
- 15 see that?

- 16 A. Yes.
- Q. And so is it fair to say that this is an
- 18 example of an SOM report that Mallinckrodt had created
- 19 and apparently sent to the DEA in 2003?
 - A. That's what it appears to be.
- Q. And do you have any understanding of how
- 22 Mallinckrodt identified the suspicious orders that
- 23 appeared here?
- A. Through the use of the algorithms that

Page 90 1 they were utilizing. Q. And turning back to your testimony earlier Q. So it's your testimony that Mallinckrodt

- 3 utilized an algorithm as of 2003?
- A. Yes.
- 5 Q. And separate and apart from the algorithm,
- 6 do you know whether or not Mallinckrodt utilized any
- 7 other elements to identify a suspicious order at that
- 8 time?
- 9 MR. O'CONNOR: Objection to form.
- 10 Objection to form.
- 11 A. The -- every order was being reviewed by a
- 12 customer service rep. So in addition to the
- 13 algorithms, every order was reviewed by customer
- 14 service.
- 15 BY MR. KO:
- 16 Q. And how do you know that? Is that what
- you were told by counsel?
- 18 MR. O'CONNOR: Objection. Instruct you
- not to answer what we discussed. 19
- BY MR. KO:
- 21 Q. Earlier you said --
- 22 MR. O'CONNOR: (Inaudible) privilege.
- 23 BY MR. KO:
- 24 Q. Earlier you said that you did not recall

- 2 just a moment ago, when you were saying the customer
- Do you know whether or not that review was
- ever documented in any way?

3 service reps would sometimes review the order.

- A. I do not, but they reviewed every order.
- Q. And when you say they reviewed every order, are you saying that they reviewed every single
- order ever entered into between Mallinckrodt and a
- wholesaler distributor customer?
- 11 A. I'm saying that they reviewed every one of these orders that had the peculiar order report.
 - Q. I see. So outside of the peculiar order
- algorithm system, was there a separate system or
- protocol for a customer service rep to identify an
- order as being potentially peculiar?
- 17 MR. O'CONNOR: Objection to form.
- 18 A. Not that I'm aware of.
- 19 BY MR. KO:
- 20 Q. So in other words, the customer service
- rep or individual that would review an order is doing
- so only after it is identified as peculiar by a certain
- algorithm; is that accurate?
- 24 MR. O'CONNOR: Objection to form.

Page 91

- 1 ever seeing an SOM program prior to a certain time
- period. Is that accurate?
- 3 MR. O'CONNOR: Objection. Form.
- 4 A. I didn't recall seeing -- I believe the
- 5 question was a written report, so I didn't recall
- 6 seeing a written report.
- 7 BY MR. KO:
- 8 Q. So if you've never seen a written report,
- 9 how did you gain an understanding of what the SOM
- 10 program was like prior to when Mallinckrodt ever had a
- 11 written report?
- A. So I was advised by another employee.
- 13 Q. And which employee?
- 14 A. Karen Harper.
- 15 Q. And when did she advise you of that?
- 16 A. January of this year.
- 17 So prior to January of 2019, did you ever
- 18 have an understanding of what the SOM program was like
- prior to when Mallinckrodt had a written report -- or
- written policy? Excuse me.
- 21 MR. O'CONNOR: Objection. Form.
- 2.2 A. Outside of what she might have discussed
- 23 with me in this e-mail, no.
- 24 BY MR. KO:

A. That's my understanding.

- 2 BY MR. KO:
- Q. And so earlier we had talked about a
- 4 multitiered structure or a two-tiered structure, and we

Page 93

- 5 had identified or we had discussed the concept of first
- an order being triggered pursuant to an algorithm and
- then subsequently being identified as peculiar.
- 8 Do you recall that discussion?
- A. Yes.
- 10 Q. And after that review, then an order
- 11 was -- or excuse me.
- 12 After that report was created, the order
- would then be analyzed to determine whether or not it
- was suspicious; right?
 - A. Correct.

15

20

- 16 Q. And I'm just trying to get an
 - understanding of when the customer service rep would
- review the order, and it would be after the order was
- identified as peculiar; correct?
 - A. That's my understanding.
 - Q. And they would not review -- just so the
- 22 record is clear, they would not review every order
- ²³ prior to any identification of the order being
- 24 peculiar; is that correct?

Page 94 1 MR. O'CONNOR: Objection to form. 1 MR. O'CONNOR: Objection. 2 A. Correct. 2 BY MR. KO: 3 BY MR. KO: Q. So again, as of April 2014, Eileen, a 4 member of the SOM team, is identifying to Karen, also a Q. And so going -- just looking back at this 5 document, the orders that appear here -- it's your 5 member of the SOM team, that the earliest SOM report 6 testimony that it's your belief these orders were that Mallinckrodt has access to is as of 2003; is that ⁷ identified pursuant to whatever algorithm was in place accurate? 8 8 as of 2003; correct? MR. O'CONNOR: Objection to form. A. I'm sorry. Could you restate that one A. That's my understanding. 10 Q. And these orders then would not have been 10 more time? 11 identified through any other process other than the 11 BY MR. KO: peculiar order algorithm that was in place; correct? 12 Q. Sure. As of April 2014, Eileen, a member 13 A. Not that I'm aware of. 13 of the SOM team, is identifying to Karen, also a member of the SOM team, that the earliest SOM report that 14 Q. You can set that aside. I'm going to hand Mallinckrodt had access to is as of 2003. Is that 15 you a copy of what's going to be marked as Gillies 16 Exhibit -accurate? 17 17 MR. O'CONNOR: Same objection. MS. GAFFNEY: 6. 18 BY MR. KO: 18 A. She's saying the attached report is from 19 Q. -- 6. And for the record, this is --19 there. 20 BY MR. KO: ends in Bates 7026341. 21 21 [Exhibit Mallinckrodt-Gillies-006 Q. Is there any reference to a SOM report 22 prior to 2003? marked for identification.] 23 23 Q. And this is a letter from Eileen Spaulding A. Not in this e-mail, no. 24 to Karen Harper dated April 24th, 2014, and you said Q. And Ms. Spaulding also indicates that Page 95 Page 97 1 earlier that Eileen is a member of the SOM team; is 1 there -- she does recall having an SOM system in place 2 that correct? 2 starting in 2001. Is that accurate? 3 A. She is. A. Yes. Q. And she's also a member of the DEA Q. And do you have any reason to dispute the 4 compliance group? 5 veracity of this e-mail? A. She is. 6 6 A. No. 7 Q. And similarly, Karen Harper is also a MR. O'CONNOR: Objection to form. 8 member of the DEA compliance group and the SOM team? 8 BY MR. KO: 9 A. Yes. Q. Have you seen any documents that suggest 10 Q. And Eileen indicates to Karen that, quote, 10 an SOM system in place prior to 2001? 11 I can recall having a suspicious order monitoring 11 A. Not that I can recall. system in place of some type with the start of Q. Have you seen any documents that indicate 13 distribution activities from Hobart 2001, end quote. 13 an SOM report prior to 2003? 14 Did I read that correctly? 14 A. Not that I can recall. 15 A. Yes. O. You can set that aside. Now, is it Q. So -- and let me continue. However, the accurate to state that Mallinckrodt made substantial 16 17 attached is the earliest SOM report that I have in my changes to its SOM policy between the 2008 to 2011 time e-mail system. At this time the reports were being 18 period? generated monthly. The attached report is for December 19 MR. O'CONNOR: Objection to form. A. We were always looking to enhance the 20 2013 orders that were reviewed. 20 21 And I believe she means to reference 21 program. 22 December 2003, but we can go over that later. But did 22 BY MR. KO: 23 I read that portion of the e-mail correctly? 23 Q. So is it accurate to state that during 24 A. Yes. 24 the 2008 through 2011 time period, Mallinckrodt made

Page 98 1 substantial revisions to its SOM program? 1 document, this indicates, does it not, that the 2 MR. O'CONNOR: Objection to form. 2 suspicious order monitoring team start date was March 3 3 28th, 2008? A. So there were changes made. 4 BY MR. KO: A. That's what contained on that line, but 5 Q. And would you agree with me that there 5 later it says it's an upgrade to Mallinckrodt's were substantial changes? existing SOM program, so if there's an existing SOM MR. O'CONNOR: Objection to form. 7 program, then there's got to be team members that are 8 A. I don't know that I would characterize it working on that program. as substantial. Q. Well, I understand the difference 10 BY MR. KO: 10 between -- well, I understand your point about a 11 11 program, but the fact that there is a program in place, Q. How would you characterize it? 12 A. That there were changes made to the SOM does that necessarily mean that there was a team in 13 program with the more experience that they had and the place as well? more information they got. 14 A. Yes. Q. And the changes were made with the intent 15 Q. And have you seen any documents predating 16 to improve and enhance the system, as you said; 16 March 28th, 2008, that reflect an official team to the 17 correct? suspicious order monitoring system that Mallinckrodt 18 A. Yeah, to enhance the system. Correct. 18 had? 19 19 Q. I'm going to hand you a copy of what's MR. O'CONNOR: Objection to form. going to be marked as Gillies Exhibit 7. 20 A. So there were team members. 21 [Exhibit Mallinckrodt-Gillies-007 21 BY MR. KO: 22 22 marked for identification.] Q. So is it your testimony today that were 23 Q. And for the record, this is a document 23 team members of the suspicious order monitoring team 24 titled suspicious order monitoring team charter, with prior to March 2008? Page 99 Page 101 1 Bates ending in 496062. A. Yes. So I know earlier we had discussed whether Q. And who were they? 3 or not you were aware of when Mallinckrodt first began A. I don't know the names of who was 4 its SOM team. 4 involved, but we had an algorithm system. We had the 5 Does this document accurately reflect that 5 customer service reps. Karen Harper. DEA compliance 6 the SOM team began on March 28th of 2008? was part of that SOM team. 7 MR. O'CONNOR: Objection to form. Q. And how do you know that there was -well, first of all, we've established that you haven't A. I'm sorry. Could you repeat the question? I'm finished reading this document now. seen any documents that reflect an SOM team prior to 10 BY MR. KO: 10 March 2008; is that accurate? 11 11 Q. Sure. Does this document accurately MR. O'CONNOR: Objection to form. reflect that the SOM team began on March 28th, 2008? 12 A. A document that lists team members? MR. O'CONNOR: Objection to form. 13 Correct. 13 14 A. No. 14 BY MR. KO: 15 BY MR. KO: 15 Q. And so how do you have knowledge regarding the composition of an SOM team prior to March of 2008? 16 Q. Have you -- at the very beginning of this 16 17 document -- first of all, it's titled suspicious order A. Because there was an SOM program. 18 monitoring team charter; is that accurate? Q. Other than -- and you learned that there 19 A. Yes. was an SOM program through your conversations with Karen Harper; is that accurate? 20 Q. Do you recall -- is there a team charter 21 in place currently for the SOM team? 21 A. Yes.

22

24 accurate?

Q. And with respect to this particular

23 is called a charter or anything, so --

A. I don't know that there -- the procedure

22

24

Q. And you have not seen any documents

23 reflecting an actual SOM program prior to 2008; is that

Page 102 1 MR. O'CONNOR: Objection to form. 1 referring to this team as outlined in this charter? 2 A. No. A. Yeah, I believe that was your earlier 3 BY MR. KO: 3 question, to clarify that we had a team previous to Q. You have seen documents reflecting an SOM 4 this based on the SOM program. So from this team. program prior to 2008? Q. Separate and apart from this document --A. I mean, you just showed me a document that 6 let's pretend that the document doesn't exist -- how 7 had a peculiar order report, and this came from the SOM 7 long was Ms. Harper the team leader of the suspicious order monitoring program team at Mallinckrodt? 8 program. Q. And separate and apart from whether or not MR. O'CONNOR: Objection to form. 10 10 there was an SOM report, did you review or have any A. So I don't know all the dates. I'm sorry. 11 understanding in the documents you reviewed in 11 BY MR. KO: connection with this deposition of the team members 12 Q. Do you know -- do you have any 13 that were part of that SOM program? 13 understanding of whether or not she was the team leader 14 A. No. prior to 2008? 15 15 Q. And do you have an understanding of MR. O'CONNOR: Objection to form. 16 whether or not there was any written policy governing 16 A. Yes. the SOM program prior to 2008 at Mallinckrodt? 17 BY MR. KO: 18 MR. O'CONNOR: Objection to form. 18 Q. And how did you gain that understanding? 19 19 A. No. A. From Karen. 20 And did she tell you how long she was the 20 BY MR. KO: 21 Q. So at least we can agree, for purposes of team leader prior to 2008? 22 this document, it indicates that the team's start date 22 A. She did not. 23 for this particular suspicious order monitoring team is 23 And how about after 2011? Did you have 24 as of March 2008; is that accurate? 24 any conversations with her about how long she was a Page 103 Page 105 1 team leader of the SOM team after 2011? 1 A. For this particular team, yes. And the team leader is Karen Harper; is A. I did not. 3 that accurate? Q. Who is the team leader currently of the -of Mallinckrodt's SOM program? 4 A. That's what this document says. 5 Q. And is it your -- has Karen Harper always MR. O'CONNOR: Objection to form. 6 been the team leader of the suspicious order monitoring A. Don Lohman. 6 7 BY MR. KO: team at Mallinckrodt? Q. And how long has he been the team leader? 8 MR. O'CONNOR: Objection to form. 9 A. No. Since sometime in 2011. Q. And was Ms. Harper -- did she continue to 10 BY MR. KO: 10 11 be a member of the SOM team after 2011? 11 Q. And during what periods of time was she 12 the team leader of the SOM team? 12 A. Yes. 13 A. So on this team, from that date until 2011 13 Q. And you can actually set that document aside. I'm going to hand you a copy of what will be 14 time frame. marked as Gillies Exhibit 8. 15 Q. So the record is clear, your testimony is 16 that Karen Harper was the team leader of the SOM MS. GAFFNEY: 8. 16 program from approximately March of 2008 to 2011? 17 [Exhibit Mallinckrodt-Gillies-008 18 A. For this team. Some of the members could 18 marked for identification.] 19 have changed through that time, though. 19 BY MR. KO: 20 Q. Was there another suspicious order 20 Q. And for the record, this ends in Bates monitoring team between the 2008 and 2011 time period? 7053963. And this also reflects some notes from a 21 22 Not that I'm aware of. 22 Hobart meeting with DEA Albany on SOM and quota between 23 Q. So I'm just trying to get an 23 DEA and Mallinckrodt.

24

24 understanding. When you say of this team, you're

And Mr. Gillies, I'm happy to allow you to

| | Page 106 | Τ | Page 108 |
|--|--|--|--|
| 1 | review other portions of this document if you'd like, | 1 | that accurate to say? |
| | | 2 | • |
| | but I just want to direct you to certain portions of it. | 3 | MR. O'CONNOR: Objection to form. A. I don't know. |
| 4 | | 4 | |
| | First of all, at the top of this e-mail | 5 | |
| | there's a list of people who attended this meeting at | | Q. You have no recollection of what well, |
| 6 | both Mallinckrodt and DEA; is that accurate? | 6 | |
| 7 | A. Yes. | 7 | So it's your understanding that there was |
| 8 | Q. And both Mr. Lohman and Ms. Harper were in | 8 | 1 0 |
| 9 | attendance? | 9 | accurate? |
| 10 | A. That's what this states. | 10 | A. Yes. |
| 11 | Q. As well as Ms. Spaulding? | 11 | Q. Do you have under any understanding of |
| 12 | A. Yes. | | what provisions of the SOM program were updated during |
| 13 | Q. Now, I want to go down to the portion of | | that time? |
| 1 | these notes at the bottom of the first page regarding | 14 | A. There was an algorithm change. |
| 15 | , | 15 | Q. And what did that algorithm change consist |
| 16 | A. Yes. | | of? |
| 17 | Q. And it appears that Mr. Lohman had some | 17 | A. I believe the algorithm had a 2X, and it |
| - 1 | interactions with the DEA regarding Mallinckrodt's SOM | 18 | 1 |
| | program; is that fair? | 19 | Q. And when you say 2X, can you please |
| 20 | A. Yes. | 20 | |
| 21 | Q. And turning to Page 2 of these notes, | 21 | A. I cannot recall. |
| | there was a question apparently asked by the DEA, how | 22 | Q. Let's actually set this document aside. |
| | many orders have been deemed suspicious? Do you see | | And I'll hand you a copy of what's previously marked as |
| 24 | that? | 24 | Stewart Exhibit 1. |
| | Page 107 | | Paga 100 |
| | 1 age 107 | | rage 109 |
| 1 | A. Yes. | 1 | Page 109 A. Okay. |
| 1 2 | A. Yes. | 1 2 | A. Okay. |
| 2 | _ | 2 | _ |
| 2 3 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. | 2 | A. Okay.Q. Which for the record, it ends in Bates |
| 2 3 4 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. It was explained that this updated SOM program went | 2 | A. Okay.Q. Which for the record, it ends in Bates299558. This is a short e-mail exchange, so go ahead |
| 2 3 4 5 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. It was explained that this updated SOM program went into place on 3-1-12 and no orders have been determined | 3 4 | A. Okay.Q. Which for the record, it ends in Bates299558. This is a short e-mail exchange, so go ahead and take a look at it.A. Okay. |
| 2 3 4 5 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. It was explained that this updated SOM program went into place on 3-1-12 and no orders have been determined to be suspicious since that time. | 2 3 4 5 | A. Okay. Q. Which for the record, it ends in Bates 299558. This is a short e-mail exchange, so go ahead and take a look at it. A. Okay. Q. Let me know when you're done. |
| 2 3 4 5 6 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. It was explained that this updated SOM program went into place on 3-1-12 and no orders have been determined | 2 3 4 5 6 | A. Okay. Q. Which for the record, it ends in Bates 299558. This is a short e-mail exchange, so go ahead and take a look at it. A. Okay. Q. Let me know when you're done. A. Okay. |
| 2 3 4 5 6 7 | A. Yes. Q. And the answer that either Mr. Lohman or someone in attendance at Mallinckrodt gave was none. It was explained that this updated SOM program went into place on 3-1-12 and no orders have been determined to be suspicious since that time. Did I read that correctly? | 2 3 4 5 6 7 | A. Okay. Q. Which for the record, it ends in Bates 299558. This is a short e-mail exchange, so go ahead and take a look at it. A. Okay. Q. Let me know when you're done. A. Okay. Q. So this e-mail exchange dated April 1st, |
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| | ighly Confidential "- Subject" to Page 110 | | Page 112 |
|--|---|--|---|
| 1 | A. Correct. | 1 | hired by Mallinckrodt, former DEA employee. |
| 2 | Q. Bill Ratliff is also mentioned here. Who | 2 | Q. And was he an outside contractor retained |
| | is he? | | to advise specifically on SOM obligations? |
| 4 | A. He was the former head of security for | 4 | A. Yes. |
| 5 | Mallinckrodt. | 5 | Q. And I believe he was also retained to |
| 6 | Q. And what responsibilities did he have with | 6 | advise on other Mallinckrodt DEA obligations such as |
| 7 | respect to the SOM program? | 7 | any responsibilities with respect to quota. Is that |
| 8 | A. He was part of the SOM team. | 8 | accurate? |
| 9 | Q. And what were his responsibilities? | 9 | A. I don't know that. |
| 10 | A. I can't recall. | 10 | Q. Now, Mr. Ratliff indicates that as of |
| 11 | Q. And do you know how long he was a member | 11 | April 1st, 2008, there is a need to strengthen |
| | of the SOM team? | 12 | Mallinckrodt's suspicious order identification system. |
| 13 | A. While he was employed. | 13 | Do you see that? |
| 14 | Q. While he was employed at Mallinckrodt? | 14 | MR. O'CONNOR: Objection to form. |
| 15 | A. Yeah. But I do not know what his start | 15 | A. That's what you've highlighted there, that |
| 16 | date was at Mallinckrodt. | 16 | they had the conference call with Sapienza to |
| 17 | Q. Is it your understanding that he was a | 17 | strengthen the system. |
| 18 | member of the SOM team throughout the duration of his | 18 | BY MR. KO: |
| 19 | employment? | 19 | Q. So is it accurate to state that as of |
| 20 | A. That's my understanding. | 20 | April of 2008, individuals within the SOM team at |
| 21 | Q. And what about Mr. Rausch? How long was | 21 | Mallinckrodt felt the need to strengthen Mallinckrodt's |
| | he part of the SOM team? | 22 | suspicious order monitoring program? |
| 23 | A. I do not know what his dates were. | 23 | MR. O'CONNOR: Objection to form. |
| 24 | Q. Now, we can go over some of the details of | 24 | A. I think the team was always looking to |
| | Q. 110w, we can go over some of the actains of | | 71. I think the team was always looking to |
| | 5 111 | | D 440 |
| | Page 111 | | Page 113 |
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Q. First of all, who's Frank Sapienza?

A. He was an outside contractor that was

23 that Mallinckrodt sent following its decision to stop

24 sending monthly reports to the DEA in April of 2008?

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|-------|-----|-----|---|
| Page | - 1 | - 1 | 4 |
| 1 ago | 1 | 1 | ┰ |

- A. So my understanding is that it was April
- 2 of 2008 that we stopped sending them, not October that
- 3 was referenced in this previous document you showed me.
- 4 And then in 2012, we started sending reports to the DEA
- 5 again.
- 6 Q. So that's helpful. So there was a period
- 7 of time in which reports were not sent to the DEA; is
- 8 that accurate?
- 9 A. Yes.
- Q. And that period of time was from mid-2008
- 11 through 2012; correct?
- A. From April 2008 till some time in 2012.
- Q. And do you have a general understanding of
- 14 when in 2012 that practice resumed?
- 15 A. I don't.
- Q. And in 2012, what did those reports
- 17 consist of?
- A. I don't recall. But I believe we've given
- 19 those reports to you guys. So I just don't recall what
- 20 they were.
- Q. And when you say given those reports to
- 22 you guys, you mean that your counsel has produced those
- 23 documents in this litigation?
- 24 A. Yes. Sorry.

1 excessive order reports to the DEA; correct?

- 1 excessive order reports to the DLA, correct:
- 2 A. Whatever that time frame is from April of
- 3 2008 to 2012, yes.
 - Q. So there was -- during that time period,
- 5 Mallinckrodt did not send any type of monthly excessive
- 6 order report to DEA; correct?
 - A. Correct.
- Q. And when Mallinckrodt began to send
- 9 monthly reports again to the DEA, what happened that --
- 10 or what happened to reflect the understanding that
- 11 Mallinckrodt would then be resuming delivery of
- order -- monthly order reports to DEA?
 - MR. O'CONNOR: Objection to form.
- A. So there's a privilege here.
- MR. O'CONNOR: In that case, I would
- 16 object and instruct the witness not to answer to the
- 17 extent it would require revealing communications with
- 18 counsel on the basis of attorney-client privilege.
- 19 BY MR. KO:
- Q. So is your complete answer covered by the
- 21 privilege?
- A. On this question, yes.
- Q. So during the 2012 time period when
- 24 Mallinckrodt began resuming sending reports to the DEA,

Page 115

- 1 Q. That's okay. And were those -- strike
- 2 that.
- 3 Do you have any understanding of why there
- 4 was -- why Mallinckrodt decided not to send any reports
- 5 to DEA during that approximate three-and-a-half-year
- 6 time period?
- 7 MR. O'CONNOR: Objection to form.
- 8 A. So this would have been in response to the
- 9 December 2007 letter where DEA advised stop sending the
- 10 reports.
- 11 BY MR. KO:
- Q. But eventually Mallinckrodt resumed their
- 13 practice of sending some sort of report to DEA, as you
- 14 said, in 2012; right?
- 15 A. That's correct.
- Q. So what was it about those reports that
- 17 satisfied Mallinckrodt sufficient enough to send
- 18 letters again to the DEA? Or reports. Strike that.
- 19 MR. O'CONNOR: Objection to form.
- 20 BY MR. KO:
- Q. Let me make sure the record is -- poor
- 22 question. Let me ask it again.
- There was a three-and-a-half-year time
- 24 period in which Mallinckrodt did not send monthly

Page 117

- 1 was that when you were part of -- was that after you
- ² joined Mallinckrodt?
- 3 A. It either started right before I joined or
- 4 right after I joined.
- 5 Q. So then it's safe to say approximately in
- 6 the summer of 2012 was when Mallinckrodt resumed
- 7 sending monthly reports to DEA?
- 8 A. That's my understanding.
- 9 Q. And -- but you don't know what those
- 10 reports consist of?
- 11 A. It wasn't part of my role on the SOM team,
- 12 so no, I don't recall what they consist of.
- Q. And separate and apart from your role on
 - 4 the SOM team, you didn't review any of those reports or
- 15 gain an understanding of what those reports consisted
- of in preparation for your deposition today?
 - A. Again, I believe I was shown the
- 18 documents, but I just can't recall.
- Q. And when you say you were shown the
 - 0 documents, what documents were you specifically shown
- 21 in this context?

- A. Would have been copies of these reports.
- Q. And you have no recollection of what those
- 24 reports consisted of right now?

Page 118 1 A. I do not. Q. And the first -- one of the documents that 2 Yeah, you can set that aside. Thank you. ² she is referencing is in fact this SOM compliance 3 procedure policy; correct? A. This controlled substance SOM procedure? 4 Sorry. Bear with us. Some technical Q. difficulties. 5 Q. Yes, the attachment. 6 A. That's all right. 6 A. Yes. Okay. Yeah. 7 [Exhibit Mallinckrodt-Gillies-010 Q. So is it accurate to say -- well, let's 8 marked for identification.] take a step back. 9 Q. I'm going to hand you a copy of what's You had indicated earlier that you had 10 going to be marked as Gillies Exhibit 10. And for the 10 reviewed certain documents in preparation for this 11 record, this is an April 8th, 2008, e-mail between 11 deposition today and that you had seen some written 12 Karen Harper and Bill Ratliff ending in Bates 273892 policies; correct? 13 with an attachment. 13 A. Yes. 14 So earlier today we were discussing 14 Q. Did you review this written policy? whether or not Mallinckrodt had written policies 15 A. No. governing its SOM program. 16 Q. You did not? Okay. Is it accurate --17 Do you recall that? regardless of whether or not you reviewed this 18 A. Yes. particular one, is it accurate to state that this is a 19 Q. And you said that you had no recollection draft of Mallinckrodt's SOM policy? 20 of when or whether you've seen any of the written 20 A. That's what it appears to be, a draft. 21 policies with respect to its SOM program. Q. And this draft is dated -- well, this 22 Do you recall that? 22 draft doesn't have a date, but it's circulated on April 23 A. Prior to a certain date, was your 23 1st, 2008; correct? A. The date on the e-mail is April -- is that 24 question, so --Page 119 Page 121 Q. Right. And is that -- so this document 1 6th or 8th? ² reflects, as I alluded to earlier, an e-mail from Ms. Q. Yeah, I believe it's April 8th. So --³ Harper to Mr. Ratliff attaching an SOM draft policy; is A. Okay. 4 that accurate to say? Q. Thank you for that clarification. So this A. I'm sorry. Can I have a moment to read ⁵ first draft of Mallinckrodt's SOM program is circulated 6 as of April 8th, 2008; correct? 6 this? 7 A. Yes. Q. Sure. 8 A. Okay. I'm sorry. Go ahead. Q. And in this particular draft policy, you Q. Does the attachment contained in this see the reference to peculiar order and suspicious 10 exhibit -- the attachment that is titled DEA compliance 10 order? 11 procedure, controlled substance suspicious order 11 A. Yes. 12 monitoring -- does this reflect a draft SOM policy of Q. And is there any indication in this 13 particular draft regarding any algorithm of how a 13 Mallinckrodt? peculiar order is determined by Mallinckrodt? 14 A. Yes. 15 Q. And in the cover e-mail, there is a 15 A. Can you restate that, or repeat the 16 reference from Ms. Harper to Mr. Ratliff that she's 16 question? attaching it for his review; correct? 17 Q. Sure. Sure. I'll actually rephrase the 18 A. Yes. 18 question. 19 Q. And that she's making a start or she's 19 As of April 8th, 2008, is it accurate to 20 making a first pass at a certain document. Is that say that Mallinckrodt did not memorialize a particular 21 accurate? algorithm for purposes of defining a peculiar order?

22

23

24 BY MR. KO:

MR. O'CONNOR: Objection to form.

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23

A. Yes.

24 BY MR. KO:

MR. O'CONNOR: Objection to form.

A. Not in this document.

Page 122 1 Q. And do you have any understanding of 1 Q. And with respect to the supersedes date, ² whether or not a peculiar order algorithm was 2 there's no document that this particular draft is 3 memorialized in any way outside of this document as of 3 superseding, so that also indicates that this is 4 Mallinckrodt's first pass at a written SOM policy; 4 April of 2008? 5 MR. O'CONNOR: Objection to form. 5 correct? A. I know there was an algorithm, but I'm 6 A. It says no. 7 unaware of any report. Q. Okay. Great. You can set that aside. 8 MR. O'CONNOR: Counsel, can we take a 8 BY MR. KO: Q. In other words, just so the record is short break and then --10 clear, as far as you know, as of April of 2008 there 10 MR. KO: Sure. 11 was no separate document that governed the definition 11 MR. O'CONNOR: It's been about an hour, 12 of what constitutes a peculiar order? 12 and then do lunch --13 MR. O'CONNOR: Objection to form. 13 MR. KO: Sure. That's fine. MR. O'CONNOR: -- after a short break? 14 A. Okay -- that was a different question that 14 you just asked me. So I have no recollection of that. 15 MR. KO: Okay. THE VIDEOGRAPHER: We are going off the 16 BY MR. KO: 16 17 Q. And for purposes of this document, there's 17 record at 11:46 AM. no algorithm that's set forth in terms of what 18 [A brief recess was taken.] 19 THE VIDEOGRAPHER: We are back on the constitutes a peculiar order; correct? 20 A. Not in this document. record at 11:59 AM. 21 21 Q. And there -- as far as you know, you've BY MR. KO: 22 not reviewed any other documents during this time Q. Welcome back from the break. In front of 23 period that reflect a written policy memorializing what 23 you you have what has previously been marked as Stewart 24 constitutes a peculiar order; is that accurate? 24 Exhibit 13, which I'll represent for the record is Page 123 Page 125 1 titled DEA compliance procedure, controlled substance 1 MR. O'CONNOR: Objection to form. 2 ² suspicious order monitoring, ending in Bates 268911. A. Not that I can recall. ³ BY MR. KO: So feel free to look through this if you'd 4 like in detail, but I just have a few questions about Q. And other than this draft SOM policy, ⁵ would Mallinckrodt have any other type of written 5 this that hopefully you can answer without going 6 through all the doc -- or throughout all the language 6 document that would define the algorithm used for defining a peculiar order? 7 in it. But again, feel free to go ahead if you need 8 A. I don't know the answer to that question. 8 to.

- 9 Q. Now, at the top of this page, in the top
- 10 right-hand corner there's an indication of effective
- 11 date and supersede date, and in fact, on top of that,
- 12 revision.
- 13 Do you see those?
- 14 A. Yes.
- 15 Q. And as we discussed earlier, there's no
- ¹⁶ effective date for this because it's a draft, among
- other reasons, but do you see where it says Revision
- 18 Number 1?
- 19 A. Yes.
- 20 Q. So would it be fair to say that this is
- the SOM team's first pass at a written SOM policy? 21
- 22 MR. O'CONNOR: Objection to form.
- 23 A. Yes.
- 24 BY MR. KO:

- So this -- the date of this is May 13th,
- 10 2008; correct?
 - A. Yes.
- 12 And this appears to be a Draft 2; is that Q.
- 13 accurate?

11

- 14 A. That's what it says -- Draft 2.
 - Q. And did you review this particular draft
- written policy in connection with preparing for this
- deposition today?
- 18 A. No.
- 19 Q. And for this particular draft there is -
 - consistent with the one that we just looked at from
 - April, there are definitions of peculiar orders and
- 22 suspicious orders. Do you see that?
 - A. Yes.
- 24 Q. And as far as the peculiar order is

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| | 1 | Page 126 defined, there's no indication of an algorithm in that | 1 | Page 128 period that covers? |
| | | particular definition; is that accurate? | 2 | A. I know it was in the material that I |
| | 3 | A. It doesn't say algorithm, but meets an | 3 | |
| | | internal established criteria. | 4 | Q. Do you have an understanding of whether or |
| | 5 | Q. Is there any indication in this document | 5 | not Mallinckrodt had any kind of formal documentation |
| | | of an algorithm or a specific algorithm that | 6 | or record retention policy with respect to SOM |
| | | Mallinckrodt is utilizing for purposes of defining a | 7 | |
| | 8 | peculiar order? | 8 | period? |
| | 9 | MR. O'CONNOR: Objection to form. | 9 | MR. O'CONNOR: Objection to form. |
| | 10 | A. No mention of algorithm. | 10 | A. My recollection is yes. |
| | 11 | BY MR. KO: | 11 | |
| | 12 | Q. So is it accurate to say that as of May | 12 | Q. And what is that recollection based on? |
| | 13 | 13th, 2008, there was no algorithm that is mentioned at | 13 | A. Based on the what I learned preparing |
| | 14 | least for purposes of the draft SOM policy? | 14 | |
| | 15 | MR. O'CONNOR: Objection to form. | 15 | Q. And that and what you learned was |
| | 16 | A. It's not mentioned in this document. | 16 | |
| | 17 | BY MR. KO: | 17 | |
| | 18 | Q. And turning to the last page of this | 18 | A. Yes. |
| | 19 | document that I believe you were just at, there is a | 19 | Q. And I'm just trying to get an |
| | 20 | there's an indication that the security director and | 20 | understanding of what that specifically consisted of, |
| | 21 | DEA compliance should be responsible for maintaining a | 21 | because you're telling me that you reviewed certain |
| | 22 | file for record retention of suspicious order | 22 | things. |
| | | monitoring documents and reports. | 23 | So what did you review? |
| | 24 | Do you see that portion of the draft | 24 | |
| | | • | | · |
| - | | | - | |
| | | Page 127 | | Page 129 |
| } | | policy? | 1 | the extent we're talking about the collection of |
| | 2 | policy? A. Yes. | 2 | the extent we're talking about the collection of documents that were selected by counsel for his review, |
| - | 2 | policy? A. Yes. Q. And do you have any understanding of | 3 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been |
| | 2 3 4 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort | 3 4 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting |
| | 2 3 4 5 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and | 2 3 4 5 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. |
| | 2 3 4 5 6 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? | 2 3 4 5 6 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: |
| | 2 3 4 5 6 7 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? A. Yes. | 2 3 4 5 6 7 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: Q. Do you want me to repeat my question or |
| | 2 3 4 5 6 7 8 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? A. Yes. Q. And in what type of what type of | 2 3 4 5 6 7 8 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: Q. Do you want me to repeat my question or rephrase? |
| | 2 3 4 5 6 7 8 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? A. Yes. Q. And in what type of what type of retention policy did Mallinckrodt utilize to maintain | 2 3 4 5 6 7 8 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: Q. Do you want me to repeat my question or rephrase? MR. O'CONNOR: Do you want to ask a more |
| | 2 3 4 5 6 7 8 9 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? A. Yes. Q. And in what type of what type of retention policy did Mallinckrodt utilize to maintain these types of documents and reports? | 2 3 4 5 6 7 8 9 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: Q. Do you want me to repeat my question or rephrase? MR. O'CONNOR: Do you want to ask a more tailored question? |
| | 2 3 4 5 6 7 8 9 10 | policy? A. Yes. Q. And do you have any understanding of whether or not Mallinckrodt did in fact keep some sort of file for record retention of SOM documents and reports? A. Yes. Q. And in what type of what type of retention policy did Mallinckrodt utilize to maintain these types of documents and reports? A. I don't recall. | 2 3 4 5 6 7 8 9 10 | the extent we're talking about the collection of documents that were selected by counsel for his review, I'm going to instruct him not to answer. We've been pretty indulgent on individuals, but we're not getting into the full selection of documents. BY MR. KO: Q. Do you want me to repeat my question or rephrase? MR. O'CONNOR: Do you want to ask a more tailored question? MR. KO: Sure. |
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Page 130 Page 130

- 1 Q. Yeah, I understand the documents were
- 2 provided to you, and I'm asking you which documents did
- 3 you review to help inform you that Mallinckrodt had a
- 4 formal documentation or document retention policy with
- 5 respect to its SOM program in the 2008 through 2011
- 6 time period?
- A. So there were e-mails and policies,
- 8 procedures, and a list of documents that were provided
- 9 to you in this matter.
- Q. And which -- let's take the policies and
- 11 procedures. Which policies and procedures are you
- 12 referring to?
- 13 A. I don't recall.
- Q. And let's take the e-mails. Which
- 15 e-mails -- were there e-mails that actually indicated
- 16 that there was a formal document retention policy with
- 17 respect to SOM records and documents from the 2008 and
- 18 2011 time period?
- 19 A. I--
- MR. O'CONNOR: Again, I'm going to object.
- 21 We're not going to get into individual document by
- 22 document everything he reviewed.
- MR. KO: I understand that.
- MR. O'CONNOR: I'll instruct the witness

- 1 very high level.
 - A. My recollection was it was just the
- 3 categories of documents that were provided to you guys
- 4 from the peculiar order reports.
- 5 BY MR. KO:
 - Q. Other than --
 - A. And there were other documents, too, that
- 8 were provided to you guys that I reviewed.
- 9 Q. But to be clear, did any of these
- documents that you review suggest that Mallinckrodt had
- 11 some sort of formal document or retention policy with
- 12 respect to Mallinckrodt SOM reports or documents during
- 13 the 2008-2011 time period?
 - A. I don't recall ---
- MR. O'CONNOR: Objection to form.
 - A. I don't recall a document that says that.
- 17 BY MR. KO:

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- Q. You can set that one aside.
- 19 [Exhibit Mallinckrodt-Gillies-009
- 20 marked for identification.]
- Q. I'm going to hand you a copy of what's --
- 22 we're going a little bit out of order, but this is
- 23 Gillies Exhibit 9. And for the record, this ends in
- 24 Bates 419993.

Page 131

- 1 not to answer on the basis of attorney-client
- ² privilege.
- 3 BY MR. KO:
- 4 Q. So were there -- without discussing the
- 5 details of the specific e-mails, is it your testimony
- 6 that you reviewed e-mails that suggested that
- 7 Mallinckrodt had a formal document retention policy
- 8 with respect to SOM documents and reports in the 2008
- 9 and 2011 time period?
- 10 A. I don't recall that.
- Q. So you don't recall seeing any e-mails
- 12 that reflect -- so just so the record is clear, yes or
- 13 no, do you recall reviewing e-mails from the 2008 and
- 14 2011 time period that reflect a document retention
- policy with respect to SOM documents and records?
- 16 A. No.
- Q. And then just the last part of your
- 18 answer, you said that you reviewed certain e-mails and
- 19 policies and procedures and other documents provided to
- 20 our side.
- 21 Can you generally describe what that third
- 22 category consisted of without getting into the details
- 23 of what was selected by counsel?
- MR. O'CONNOR: Again, you can respond at a

- And so Mr. Gillies, is it accurate to say
- ² that this document reflects a Draft 3 published June

Page 133

- ³ 2nd, 2008, of Mallinckrodt's SOM policy?
 - A. Yes.
 - Q. And similar to the question I asked with
- 6 respect to the prior Draft 2 from May. In the peculiar
- ⁷ order definition, there's no indication of an algorithm
- order definition, there is no indication of an argon
- 8 that Mallinckrodt is utilizing to define a peculiar
- ⁹ order; is that correct?
- A. Again, I'd have to go through this to make
- sure there's no reference to that.
- Q. Sure. Well, let me just ask you a narrow
- 13 question.

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17

- A. Okay.
- Q. On the definitions page at the bottom of
- 16 the first page.
 - A. Okay, I'm sorry.
- Q. The definition appears to be similar to
- 19 the previous two drafts we reviewed; correct?
 - A. Yes.
- Q. And in that particular definition of a
- 22 peculiar order, there's no reference to what the
- 23 algorithm Mallinckrodt would utilize to define a
- ²⁴ peculiar order; correct?

Page 134 1 A. Correct. Correct. Q. And the portion of this policy that states 2 Q. Now, going back to the top of this e-mail, 2 that it is fundamental for the DEA registrant to 3 in the purpose section, the second sentence states, 3 understand the normal and expected transactions 4 quote, DEA cannot, will not tell a DEA registrant if an 4 typically conducted by those customer -- what is your 5 order is legitimate and/or if an order should be understanding of what those transactions consist of? shipped. A. So I --7 7 Did I read that correctly? MR. O'CONNOR: Objection to form. 8 8 A. I interpret this between Mallinckrodt and A. Yes. 9 Q. And it continues to say it is fundamental the customer. 10 for sound operations that DEA registrants take BY MR. KO: 11 reasonable measures to identify their customers, 11 Q. So is it your understanding that the, 12 understand the normal and expected transactions quote, normal and expected transactions, end quote, are 13 typically conducted by those customer, and consequently transactions between Mallinckrodt and its customers? 14 identify those transactions that are suspicious in 14 That's how I read this. 15 15 nature. Q. And so in order -- is it your testimony 16 Did I read that correctly? 16 then that Mallinckrodt's suspicious order monitoring 17 system was only designed to identify the orders that A. Yes. 18 Q. Now, with respect to that second -- or the were suspicious as between Mallinckrodt and its 19 last sentence that I just read, is it accurate to say distributors? 20 that Mallinckrodt has memorialized in this particular 20 MR. O'CONNOR: Objection to form. draft the understanding that it should know their 21 A. That's what the regulation is, yes. 22 customers in connection with implementing an SOM 22 BY MR. KO: 23 23 program? Q. And do you believe that -- well, let's 24 MR. O'CONNOR: Objection to form. fast-forward to today's version of Mallinckrodt's SOM Page 135 Page 137 A. Yes. 1 1 program. 2 BY MR. KO: Doesn't Mallinckrodt's current iteration 3 Q. And would you also agree with me that this 3 of the SOM program try and understand where 4 particular language reflects an understanding by 4 Mallinckrodt pills are going after the transaction 5 Mallinckrodt that they would need to know their occurs between Mallinckrodt and the distributor? 6 customers' transactions that they enter into as well; MR. O'CONNOR: Objection to form. 7 correct? A. After the transaction between Mallinckrodt 8 MR. O'CONNOR: Objection to form. and its customer? I just want to make sure I A. It says identify those transactions that understood your question correctly. 10 are suspicious in nature. 10 BY MR. KO: 11 BY MR. KO: 11 Q. The question is doesn't Mallinckrodt's 12 Q. And so would you agree with me that this current iteration of its SOM program try and understand 13 language reflects an understanding by Mallinckrodt that where Mallinckrodt pills are going after the 14 they would need to know the details of the customers' transaction between Mallinckrodt and the distributor? 15 15 transactions regarding Mallinckrodt opioids? A. Yes. MR. O'CONNOR: Objection to form. 16 16 MR. O'CONNOR: Same objection. 17 A. Between Mallinckrodt and the customer? 17 BY MR. KO: 18 BY MR. KO: Q. And so in other words, Mallinckrodt's 19 Q. No, between Mallinckrodt's customer and a current iteration of its SOM program tries to pharmacy and/or clinic that the wholesale distributor understand knowledge of Mallinckrodt's customer's

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customer; is that accurate?

MR. O'CONNOR: Same objection.

21 is dealing with.

24 BY MR. KO:

A. No.

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MR. O'CONNOR: Objection to form.

24 regulation calls for here in trying to accomplish that.

A. Yes, we're going above and beyond what the

Page 138 1 BY MR. KO: A. So in our anti-diversion efforts, this is 2 Q. And turning back to the purpose statement 2 one of those times that we were going above and beyond ³ of this particular draft that's dated June of 2008. 3 what was called for in the regulations. 4 BY MR. KO: Is it your testimony that you don't Q. Well, that's not the question I asked. 5 believe this draft policy reflects an understanding of Mallinckrodt to try and know its customer's customer? A. I'm sorry. MR. O'CONNOR: Objection --Q. Is it your test --8 A. No, there was no regulation at that time. 8 A. I misunderstood your question. 9 BY MR. KO: Q. Sure. Is it your testimony today that you 10 Q. I understand that there was no regulation. 10 believe that it would be appropriate to not follow the 11 I'm just talking specifically about this document. advice of the DEA to know your customer's customer as 12 of July 2010? A. Okay. So my interpretation of this 13 document is between Mallinckrodt and its customer --MR. O'CONNOR: Objection to form. 14 14 the wholesaler distributor. A. I'm telling you there's no regulation that requires us to do this, but we do do it. 15 Q. Understood. And are you aware of any --16 earlier we had discussed that document that had a BY MR. KO: 17 chronology that Ms. Harper summarized for you. Q. I understand what your testimony is with 18 Do you recall that document? respect to whether or not there is a regulation, but my 19 MR. O'CONNOR: Objection to form. question is simply whether or not you believe it would 20 be appropriate for Mallinckrodt to not follow the A. Are you talking about the one that ends in 21 6623? I'm sorry. Is that -advice of the DEA regarding its advice that you should 22 BY MR. KO: know your customer's customer. 23 23 Q. Yes. MR. O'CONNOR: I'm going to object to form 24 and asked and answered. This is the third time. 24 A. Okay. I just want to make sure we're on Page 139 Page 141 1 the same page. A. So I have a legal --2 BY MR. KO: 2 Q. Sure. 3 A. Okay. Q. You can answer. 4 Q. So we had discussed that you had agreed A. I have a legal question. 5 that Mallinckrodt knew at least as of July 2010 that it Q. Why don't you answer -- try and answer the 6 had an obligation to know its customer's customer? question first. 7 MR. O'CONNOR: Objection to form. MR. O'CONNOR: If you believe questions 8 A. So we didn't have an obligation to know 8 that concerns privilege, then we can go off the record 9 our customer's customer, but we were being informed by and talk about it. 10 the DEA in St. Louis that that's something we should be 10 BY MR. KO: 11 11 looking at. Q. Let --12 BY MR. KO: A. Yes, I actually -- I do believe there's a 13 Q. So as of -- we had discussed how as of 13 legal issue that is problematic. 14 July 2010 you had been advised by the DEA that you 14 MR. O'CONNOR: Okay. should know your customer's customer; correct? 15 A. I just want to get a clarification. A. Yes, but there's still no regulation. MR. O'CONNOR: Then I'd ask that we either 16 16 17 O. I understand -move off the question or we can take a break. 18 A. Okay. 18 A. It should be really quick. Q. -- that your testimony is that there's no 19 19 BY MR. KO: 20 regulation or you believe that there's no obligation, 20 Q. Yeah, let's not take a break. 21 but would it be appropriate, Mr. Gillies, if 21 A. Okay. 22 Mallinckrodt did not follow the advice of DEA at the 22 Q. You can discuss it with your counsel over 23 time? 23 the lunch break. We can go back on it. 24 MR. O'CONNOR: Objection to form. 24 A. Okay.

- 1 Q. Do you recall seeing any documents or
- ² reviewing any documents that suggest that the DEA had
- 3 advised Mallinckrodt of knowing their customer's
- 4 customer in the 2008 time period?
- 5 A. No.
- 6 Q. Do you recall seeing any documents other
- ⁷ than the document that's in front of you which
- 8 indicates Ms. Harper's comments to you regarding DEA
- 9 advice regarding knowledge of customer's customer --
- 10 strike that. Let me ask again.
- Prior to 2010, have you seen any documents
- 12 that reference an obligation or advice by the DEA
- 13 regarding Mallinckrodt knowing their customer's
- 14 customer?
- A. Prior to this time frame?
- Q. (Nodding "yes.")
- 17 A. No.
- Q. And then going back to the Draft 3 that we
- 19 were discussing a moment ago.
- 20 A. Okay.
- Q. Now, I know that we had discussed -- first
- 22 of all, you agree with me that this is a draft;
- 23 correct?
- A. It says Draft 3.

Page 143

- Q. And if you look, for example, like on Page
- 2 4, which we'll turn to here, there are still question
- 3 marks and blanks with respect to what to include in
- 4 this particular draft; correct?
- 5 A. Yes, I see those now.
- 6 Q. And in that particular section at the top
- ⁷ of Page 4, I believe there is a reference to an
- ⁸ algorithm to try and define a particular peculiar
- ⁹ order.
- Do you see that portion of draft policy?
- 11 A. Yes.
- Q. So is it accurate to say that this
- 13 particular draft is the first time that Mallinckrodt
- 14 tries to incorporate reference to an algorithm into its
- ¹⁵ written draft SOM policy?
- MR. O'CONNOR: Objection to form.
- A. So I don't recall whether there was
- 18 anything written prior to this, but --
- 19 BY MR. KO:
- Q. So is it fair to say that --
- A. But we did have an algorithm.
- Q. I understand that you testified at length
- 23 that you believe there was an algorithm, but in terms
- ²⁴ of an actual algorithm being memorialized in writing,

- Page 144
- 1 do you recall seeing anything prior to June of 2008
- 2 that reflects a written memorialization of the
- 3 algorithm utilized by Mallinckrodt?
- 4 MR. O'CONNOR: Objection to form.
- A. I can't recall that.
- 6 BY MR. KO:
 - Q. You can set this one aside.
- 8 A. Okay.

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- 9 Q. We'll move on to Gillies -- now back on
- ¹⁰ track. Gillies Exhibit 11.
 - [Exhibit Mallinckrodt-Gillies-011
- marked for identification.]
 - Q. And for the record, this is titled DEA
- compliance procedure controlled substance suspicious
- order monitoring, Draft 4, ending in Bates 296382.
 - So Mr. Gillies, this particular document
- 17 reflects in the top right-hand corner that it is Draft
- 18 4, published July 8th, 2008; correct?
- A. Correct.
- Q. And so this appears to be the fourth
- 21 iteration of the documents that we've been going over;
- 22 correct?
- 23 A. Yes.
- Q. And by the way, do you have any

Page 145

- 1 understanding of -- well, the originator of this
- ² document is Karen Harper. Do you see that?
- 3 A. Yes.
- 4 Q. And I'll represent to you that in the
- 5 previous three versions that we looked at she was also
- 6 the originator.
- 7 Do you have any understanding of who Ms.
- 8 Harper circulated these draft policies to?
- 9 A. I do not.
- Q. Do you have any understanding of whether
- 11 or not these draft procedures were circulated to anyone
- 12 outside of the DEA compliance team?
- 13 A. I believe -- yes.
 - Q. And who outside of the DEA compliance team
- were these draft procedures circulated to?
- 16 A. Bill Ratliff.

14

17

- Q. And correct me if I'm wrong, but I believe
- you told me that he was part of the DEA compliance
- 19 team, or was he not?
- MR. O'CONNOR: Objection to form.
- A. I did not say that.
- 22 BY MR. KO:
 - Q. He was just part of the SOM team?
- A. That's correct.

- Q. So Bill Ratliff was never part of the DEA
- 2 compliance team?
- 3 A. I didn't say that either.
- 4 Q. I see.
- 5 A. I'm not aware of that.
- 6 Q. Understood.
- A. But he was security, and then you had DEA
- 8 compliance.
- 9 Q. Understood. Other than Mr. Ratliff, are
- 10 you aware of anyone else that these draft DEA
- 11 compliance procedures would have been circulated to?
- A. I'm unaware of who else they went to.
- Q. Now, in the scope section of this
- 14 particular draft, there's a reference to the fact that
- 15 this particular draft applies -- I'll just read it so
- 16 the record is clear.
- Scope, applies internally to Covidien
- 18 customer service group, information services group, DEA
- 19 compliance, and security for monitoring of controlled
- 20 substance orders received electronically or manually,
- 21 bulk or finished dosage products, for all active
- 22 accounts, new or established, from order placement to
- 23 shipment.
- 24 Did I read that correctly?

- 1 the 222 forms to make sure that what the customer
 - 2 address and the ship to address in our records and
 - 3 stuff matched. That was one of the SOM steps for bulk.
 - 4 BY MR. KO:
 - 5 Q. Okay. So that -- to be clear, the address
 - 6 verification form was a feature unique to the bulk SOM
 - 7 program? Is that your testimony?
 - A. Yeah, for the 222s. Yes. Uh-huh.
 - 9 Q. Through the 222 forms?
 - 10 A. Correct.
 - Q. And at any time in Mallinckrodt's history,
 - 12 are you aware of whether or not there was a separate
 - 13 bulk SOM program?
 - MR. O'CONNOR: Objection to form and
 - 15 scope.

22

- A. Again, I'm unaware of a separate one, so
- 17 the SOM program that I'm aware of included both.
- 18 BY MR. KO:
- Q. I see. So as far as your understanding,
- 20 Mallinckrodt's SOM program governed both its bulk
- 21 product and its dosage products; correct?
 - A. Correct.
- Q. And at least for purposes of this draft
- 24 procedure, it seems to make clear that the SOM program

Page 147

- 1 A. Yes.
- Q. So focusing on the portion that indicates
- ³ bulk or finished dosage products, what is the
- 4 difference -- can you explain to the court what the
- ⁵ difference is between the two?
- 6 A. Bulk -- the bulk products are at our St.
- ⁷ Louis facility. These are the manufacturing, and the
- 8 finished dosage products is at our Hobart facility for
- ⁹ the actual manufacturing of the tablets.
- Q. So in other words, is it fair to say that
- 11 Hobart is where Mallinckrodt converts the actual
- 12 product into a pill, for example? Is that correct?
- 13 A. Correct.
- Q. And the St. Louis facility is where
- 15 Mallinckrodt processes and manufactures the raw
- 16 product; correct?
- 17 A. Correct.
- Q. And so do you have any understanding
- 19 whether or not Mallinckrodt ever had a separate SOM
- 20 program with respect to its bulk product relative to
- 21 its dosage products?
- MR. O'CONNOR: Objection to form.
- A. I don't believe it was separate, but as it
- ²⁴ applied to bulk, there were address verifications from

- Page 149
- 1 is both for bulk and finished dosage products; correct?
- 2 A. Correct.
- ³ Q. For Mallinckrodt's current SOM program, is
- 4 there any sort of distinction or delineation made
- 5 between Mallinckrodt bulk and dosage products with
- 6 respect to SOM?
- 7 MR. O'CONNOR: Objection to form.
- 8 A. No.
- 9 BY MR. KO:
- Q. Now, turning to the next page, Page 2 of
- 11 this particular policy, again we see definitions of
- 12 both peculiar and suspicious orders. Do you see that?
- 13 A. Yes.
- Q. So is it accurate to say that this
- particular draft has a definition of a peculiar order
- 16 that's consistent with the others, and it does not
- 17 specifically identify the peculiar order algorithm; is
- 18 that correct?
- MR. O'CONNOR: Objection to form.
- 20 A. Yes.
- 21 BY MR. KO:
- Q. And so is it accurate to state that as of
- ²³ July 8th, 2008, Mallinckrodt had not incorporated an
- 24 algorithm into its SOM policy? Is that accurate?

Page 150 1 MR. O'CONNOR: Objection to form. Q. So you don't have an understanding of 2 A. No. 2 what -- your testimony is that you don't have an 3 understanding of what that algorithm consisted of, but 3 BY MR. KO: Q. For purposes of the written policies that 4 you believe that there was an algorithm that was 5 Mallinckrodt was attempting to create, is it accurate 5 utilized at the time? 6 to say that there is no definition of -- or there's no A. That's correct. 7 indication in this document of a specific algorithm Q. And separate and apart from whether or not 8 that's utilized for purposes of identifying a peculiar 8 there was an algorithm utilized, for purposes of this 9 order? particular document, the algorithm is not spelled out in this particular draft policy; correct? 10 MR. O'CONNOR: Objection to form. A. Sorry. I'm going to have to read this 11 11 A. Correct. 12 document to see whether that's an accurate statement or 12 You can set that one aside. 13 Okay. 14 BY MR. KO: 14 And I'll hand you a copy of what's going 15 Q. Sure. to be marked as Gillies Exhibit 12. 16 A. So --[Exhibit Mallinckrodt-Gillies-012 17 17 MR. KO: And while you go over that marked for identification.] document, maybe we can -- we can shoot for like a 12:45 Q. And for the record, Gillies Exhibit 12 break for lunch. Is that good? is -- ends in Bates 4154292. 20 MR. O'CONNOR: Sounds good. 20 And Mr. Gillies, this is -- this 21 MR. KO: Okay. particular draft procedure is dated November 4th, 2009; 22 A. So there's no mention of algorithm in this correct? 23 23 document. A. Correct. 24 24 BY MR. KO: And unlike -- well, first of all, have you Page 151 Page 153 Q. So as of July 8th, 2008, is it accurate to 1 reviewed a procedure like this before? 2 state that Mallinckrodt had not yet incorporated an A. Yes. 3 algorithm into its suspicious order monitoring draft Q. And this particular procedure, unlike the policy? 4 ones that we were going over a moment ago with respect 5 MR. O'CONNOR: Objection to form. 5 to SOM algorithms or criteria in particular, this one governs the new and existing customer account setups 6 A. It's not listed in this policy. ⁷ BY MR. KO: and ongoing reviews; is that accurate to say? 8 Q. So is it -- and my question was different. A. That's what this subject is, yes. 9 A. Okay. Q. And if we go on, the purpose of this 10 Q. As of July -- yes or no -- as of July 8th, document -- one of the purposes of this document is to 11 2008, is it accurate to state that Mallinckrodt had not establish a procedure outlining the process for yet incorporated an algorithm into its suspicious order monitoring new controlled substance customer accounts 13 monitoring draft policy? and ongoing review of existing controlled substance 14 MR. O'CONNOR: Same objection. customer accounts. 15 15 A. So again, as I stated earlier, the word You see that? 16 16 algorithm is not in here, but when it refers to A. Yes. established criteria, then I believe that to be the 17 MR. O'CONNOR: Objection. 18 algorithm even though the word algorithm is not in this 18 BY MR. KO: 19 document. 19 Q. So did Mallinckrodt have -- prior to 20 BY MR. KO: 20 November of 2009, are you aware of any written policies 21 or procedures governing the process for monitoring new Q. And what was your understanding of what 22 the established criteria was as of July 8th, 2008? and existing customer accounts of Mallinckrodt? A. I don't recall the algorithm, but there is 23 A. I can't recall. 24 a reference down here to 2X. I don't recall. 24 MR. O'CONNOR: Objection to form and

Page 154 1 scope. 1 and procedures in place with respect to its duties 2 BY MR. KO: ² under the Controlled Substances Act? Q. Does the current iteration of A. Yes. 4 Mallinckrodt's SOM program have any written policy or Q. And one of those policies and procedures 5 procedure related to new and existing customer ⁵ is reflected by this draft policy; correct? MR. O'CONNOR: Objection to form. 6 accounts? 7 MR. O'CONNOR: Same objections. A. Again, I'd have to read this entire 8 A. I can't recall. document, but --9 BY MR. KO: BY MR. KO: 10 Q. Are you aware, in addition to -- so 10 Q. Well, let's take a step back to the 11 obviously this is -- well, if you look at Page 3 of question I asked before. 12 this document, there are some question marks --12 A. Okay. 13 A. Sure. 13 Q. You had indicated that there were certain 14 policies and procedures in place with respect to 14 -- with respect to what the policy should say. So this reflects that this is a draft; correct? Mallinckrodt's duties under the CSA; correct? A. I don't see draft on this document, so I'd 16 16 A. Yes. 17 17 be speculating. Q. And what did those policies and procedures 18 Q. Would you agree with me that a document consist of other than those governing its SOM 19 that includes some question marks would not be a final obligations? or formal policy? 20 A. Security. MR. O'CONNOR: Objection to form. 21 21 Q. Anything else? 22 A. Not that I can recall. 22 A. I don't believe it would be. 23 23 BY MR. KO: Q. Do you know whether or not Mallinckrodt 24 Q. And I know I asked you about prior to this ²⁴ had any policies and procedures with respect to its Page 155 Page 157 1 time period, but following November of 2009, do you 1 customer audit programs? ² recall seeing any written policies or procedures MR. O'CONNOR: Objection to form. 3 governing existing customer accounts or new customer A. Yes, I think we did. 4 accounts? 4 BY MR. KO: 5 A. Yes. Q. And was there ever a time when Q. And when -- approximately when were those 6 Mallinckrodt had a policy or procedure with respect to policies in place? 7 specific customer accounts that it had deemed to be 8 potentially suspicious? 8 A. I don't recall the dates. 9 Q. At some point after 2009, though; correct? MR. O'CONNOR: Objection to form. 10 10 That's my recollection. A. I don't recall that. 11 Q. And approximately how many policies have 11 BY MR. KO: 12 you either reviewed or has Mallinckrodt implemented 12 Q. Okay. Fair enough. You can set this one 13 since 2009? 13 aside, and I want to -- before breaking for lunch, 14 MR. O'CONNOR: Objection to form and let's just go over one more document. 15 scope. 15 A. Okay. 16 A. My recollection is that there's several 16 Q. This will be Gillies Exhibit 13. ¹⁷ that I reviewed. 17 [Exhibit Mallinckrodt-Gillies-013 18 BY MR. KO: 18 marked for identification.] 19 Q. So in addition to -- well, Mallinckrodt 19 Q. For the record, this ends in Bates 20 had certain policies and procedures with respect to its ²⁰ 4154297. And this particular document is dated 21 SOM program, as we discussed; correct? 21 November 4th, 2009. 22 A. Correct. 22 Do you see that, Mr. Gillies? 23 Q. And in addition to those policies and 23 A. Yes. 24 procedures, did Mallinckrodt also have other policies 24 Q. And this -- the subject of this particular

Page 158 Page 160 1 policy is identification and review of peculiar orders, 1 A. Correct. 2 controlled substance suspicious order monitoring 2 BY MR. KO: 3 program. Q. And this particular algorithm or formula 4 that is being utilized -- does this refresh your 4 Did I read that correctly? 5 A. Yes. 5 recollection at all as to how long prior to November 2009 Mallinckrodt may have been utilizing this formula? 6 Q. And Karen Harper continues to be the originator of this document? MR. O'CONNOR: Objection to form. 8 8 A. Yes. A. No. 9 Q. And turning your attention to the second 9 MR. KO: Okay. We can take a break for 10 page of this document, there's a reference to the 2X 10 lunch. 11 algorithm or criteria that we were discussing 11 MR. O'CONNOR: Sounds good. 12 previously; correct? A. May I take this document so I can ask that 13 A. Yes. 13 legal question? 14 Q. And the specific definition of a peculiar 14 MR. KO: You can -- let's --15 order as defined by this policy is an order that is two 15 MR. O'CONNOR: We can go off the record. 16 times the average amount of product ordered during the 16 MR. KO: Yeah, we can go off the record. previous 18 months by DEA reporting class; correct? 17 THE VIDEOGRAPHER: We are going off the 18 Yes. 18 record at 12:47 PM. 19 Q. So is it accurate to say that as of 19 [A recess was taken.] 20 November 2009 -- or strike that. 20 THE VIDEOGRAPHER: We are back on the 21 Is it accurate to say that November 2009 record at 1:37 PM. 22 is the first time there is mention of a specific 22 BY MR. KO: 23 algorithm that will be utilized to determine whether or 23 Q. Welcome back from lunch, Mr. Gillies. 24 not an order is peculiar in an SOM written policy? 24 A. Thank you. Page 159 Page 161 Q. Before we broke, we were discussing 1 MR. O'CONNOR: Objection to form. 2 2 Exhibit 13, and I just had a couple follow-up questions A. No. 3 BY MR. KO: 3 before we move on to the next exhibit. Can you turn to the top of Page 3? And at Q. Did you recall seeing any other documents 5 prior that predate November of 2009 that memorialize 5 the top of Page 3 there's a reference to -- there's a 6 the written -- or that memorialize the algorithm that 6 Number 4, and there's a reference to reviewing the 7 Mallinckrodt was going to utilize for purposes of ⁷ order based on the criteria. Do you see that? 8 defining a peculiar order? A. Number 4, yes. A. Yes, I believe there was a document that Q. And then there's some language that says, 10 you showed me earlier. Wasn't there a reference to the quote, we should probably rephrase this to something 11 algorithm in that? 11 like place the order in appropriate hold status while 12 Q. For purposes of -- I see what you're being evaluated, end quote. 13 saying, but for purposes -- I'm just asking for 13 Did I read that correctly? 14 purposes of defining a peculiar order in the draft 14 A. Yes. written policy, is this the first time you see a 15 Q. And so does that -- does this language 16 reference made to an algorithm? 16 indicate that this version is still in draft form? 17 A. Okay. In that particular definition? 17 A. I don't know that, but I think it's fair Q. Correct. 18 18 to say that. 19 A. Yes. 19 Q. So this particular document dated 20 Q. And in the prior drafts that we had seen, 11-4-2009 regarding Mallinckrodt's controlled substance 21 there was no mention to the specific algorithm that was suspicious order monitoring program appears to be a 22 being utilized for purposes of defining a peculiar draft; is that fair to say? 23 order; correct? 23 A. Yes. 24 24 Q. You can set that one aside. And I'm going MR. O'CONNOR: Objection to form.

- 1 to now hand you a copy of what will be marked as
- Gillies Exhibit --
- 3 [Exhibit Mallinckrodt-Gillies-014
- marked for identification.]
- 5 Q. This is one document, which for the record
- is a cover e-mail and an attachment, and the cover
- e-mail is Bates MNK-T1_0000264240.
- 8 And then the attachment ends in 264260,
- and I'll represent for the record and for counsel there
- ¹⁰ are a series of attachments to this cover e-mail, and
- 11 this, for efficiency purposes, is just one of the
- attachments that's referenced in the e-mail.
- 13 A. Okay.
- Q. First let's turn to the policy -- the 14
- draft policy ending in 260.
- 16 This particular policy is dated October
- 29th, 2010; correct? 17
- 18 A. Yes.
- 19 Q. And again, this is a policy that governs
- Mallinckrodt's SOM program; is that accurate?
- 21 A. Yes.
- 22 Q. And in the prior version that we were --
- 23 if you go to the -- if you turn to Page 2 of this
- 24 policy.

- 1 order history?
 - 2 A. Yes.
 - 3 MR. O'CONNOR: Objection.
 - 4 BY MR. KO:
 - Q. And do you have any understanding of why

Page 164

Page 165

- 6 this change occurred with respect to Mallinckrodt's
- peculiar order algorithm?
 - A. It's my understanding under the 2X that
- there were too many hits on the algorithm, and our
- outside DEA consultant advised that if you have too
- many hits hitting your peculiar order report and none
- of them are, you should change it to focus a little bit
- more on those that could truly be peculiar.
- BY MR. KO:
- 15 Q. And this outside DEA consultant, was that
- 16 Mr. Sapienza?
- 17 A. Sapienza. Yeah.
- 18 Q. Sapienza? Okay. And other than Mr.
- Sapienza, did Mallinckrodt obtain any other advice with
- respect to changing the algorithm from 2X to 3X?
- 21 A. Not that I'm --
- 22 MR. O'CONNOR: Object -- I'm just going to
- 23 object to the extent that involves any attorney-client
- 24 communications.

Page 163

- A. What -- I'm sorry. Which one? The 1
- current one you just gave me?
- 3 Q. Yeah, the one I just gave you.
- 4 A. Oh, okay. Okay.
- 5 Q. Sorry. I was just giving your counsel an
- 6 extra copy.
- 7 A. Oh, okay.
- 8 Q. Page 2 of this policy has a reference to
- peculiar order like the other ones; correct?
- A. Yes. 10
- 11 Q. And here you have a definition of a
- peculiar order as being one that is, quote, controlled
- 13 substance order that meets an internal established criteria of 3X the average amount of product ordered
- 15
- during the previous 12 months by DEA reporting class.
- 16 Did I read that correctly?
- 17 A. Yes.
- 18 Q. And so in the prior version we just looked
- 19 at, the peculiar order algorithm was 2X the average
- amount of product ordered during the prior 18 months by
- 21 DEA reporting class; correct?
- 22 A. Correct.
- 23 Q. So does this policy reflect a revision in
- 24 the peculiar order algorithm to 3X the prior 12-month

- A. Not that I'm aware of, other than their
- 2 experience with the previous algorithm and then the
- ³ information they got from the consultant.
- 4 BY MR. KO:
- Q. And so in addition to changing the formula
- from 2X to 3X the average amount, the time period
- 7 that's reviewed is decreased from 18 months to 12
- 8 months as well; correct?
- A. Yes.

- 10 Q. And so again, just so the record is clear,
- 11 your testimony is that the intent behind doing this was
- to minimize the amount of peculiar order reports that
- were being produced?
 - MR. O'CONNOR: Objection to form.
- A. From the experience of reviewing the
- previous algorithm reports, it was -- there were too
- many hits on the system, and an outside consultant said
- if there's too many, then it's -- and none of them were
- turning out to be suspicious, that we needed to tighten
- that up a little bit.
- 21 BY MR. KO:
- 22 Q. And the reason why you moved down from 18
- 23 months to 12 months and up from 2X to 3X is to, as you
- 24 say, tighten up the amount of orders that were reported

Case: 1:17-md-02804-DAP Doc #: 3013-11 Elled: 12/18/19 44.of 85. PageID #: 446035 Highly Confidential ty Review Page 166 Page 168 1 under the peculiar order standard? 1 regarding its SOM program; correct? 2 A. That were hitting the report; correct. A. That's what I said, yes. 3 Q. Now, turning to the cover e-mail that Q. At the beginning of this e-mail, Ms. 4 attaches this particular document, there's an e-mail 4 Harper states Howard, please revise the QSP order 5 from Karen Harper to Howard Davis dated November 18th, 5 monitoring document incorporating recent program 2010. Do you see that? enhancements with recent activities. A. Yes. Do you see that portion of the e-mail? 8 8 Do you know who Howard Davis is? A. I do. He was another outside consultant that we 9 Q. And do you have an understanding of what QSP order monitoring document is referring to? 10 hired on a contract basis. 11 Q. And was he another outside consultant that 11 A. No. 12 Mallinckrodt hired on a contract basis to specifically 12 Q. Do you have any reason to believe that Ms. 13 advise Mallinckrodt regarding its suspicious order 13 Harper is not asking Mr. Davis to revise the SOM policy monitoring program? that we were just looking at that's included as an 15 MR. O'CONNOR: Objection to form. attachment to this exhibit? A. I believe that to be the main reason. 16 MR. O'CONNOR: Objection to form. 17 BY MR. KO: 17 A. Again, I'm unfamiliar with what she's 18 Q. Do you have any understanding of what referring to as the QSP order monitoring document and 19 other reasons he may have been retained for? this attached document. I don't see a reference to 20 A. I can't recall the details in the contract that QSP, so I don't know. 21 specifically whether there were other items that he BY MR. KO: 22 Q. Fair enough. 22 would assist on. 23 23 Q. And separate and apart from the contract, A. Okay. 24 do you have any understanding of what services Howard Q. Do you have -- sure. Do you have any Page 167 Page 169 1 Davis provided when he was retained as an outside 1 understanding of whether or not Mr. Davis was ever 2 consultant outside of advice he gave on Mallinckrodt's 2 specifically asked to revise a Mallinckrodt suspicious 3 SOM program? order monitoring policy? MR. O'CONNOR: Objection to form. A. No. A. Not sure I'm understanding the question. Q. Let me quickly hand you a copy of what's going to be marked as Gillies Exhibit 15. 6 Work outside of work he was doing for Mallinckrodt? ⁷ BY MR. KO: [Exhibit Mallinckrodt-Gillies-015 Q. No, I'm only talking about with respect to 8 marked for identification.] work he did for Mallinckrodt. Q. And I apologize. I do believe this 10 A. Okay. exhibit has been referenced in other documents, but for 11 Q. So let me rephrase. Because in response purposes of today we'll just go ahead and call it 12 to my question a moment ago, you were referencing the Gillies Exhibit 15. And it reflects a November 2nd, 13 contract. 13 2010, memorandum from Howard Davis to Karen Harper 14 A. Uh-huh. ending in Bates 269399. 15 15 Q. And I don't mean to put you through a Mr. Gillies, does this document look 16 memory test of what the contract may or may not have 16 familiar to you? 17 17 said. I'm just simply asking you do you recall whether A. Yes. 18 or not Mallinckrodt utilized Mr. Davis for any other 18 Q. Is this a document that you reviewed in 19 purpose outside of advising Mallinckrodt regarding its preparation for this deposition today? 19 20 20 suspicious order monitoring program? MR. O'CONNOR: You can answer generally

21

22

24

whether you've reviewed it.

A. Yes.

23 BY MR. KO:

Q. So it's fair to say that the primary

23 reason why Mallinckrodt retained Mr. Davis was to

24 advise -- was for Mr. Davis to advise Mallinckrodt

A. Not that I can recall.

21

22

Q. And in this document, Mr. Davis makes

| 1 | Page 170 | , | Page 172 |
|--|---|--|---|
| | reference to a certain document titled Mallinckrodt | | long he was actually retained? |
| | standard operating procedure SOPC hyphen six | 2 | MR. O'CONNOR: Objection to form. |
| 3 | A. Yes. | 3 | A. My belief was less than a year. BY MR. KO: |
| 4 | Q comp 3.0. Do you see that? | 5 | |
| 5 | A. I'm sorry. That's C hyphen where are | | Q. Less than a year? |
| 6 | you at that you're referencing? Because you said a six, and I don't see a six, and I just want to make | 7 | By the way, do you know who Mr. Davis is? A. I know who he is now. |
| | sure. Is the six the S that's there? | 8 | |
| 8 | | | Q. You didn't know him did you know him |
| 10 | Q. Sure. I may have misspoke. | 10 | at the time you joined Mallinckrodt in 2012, did you know of Howard Davis? |
| 11 | A. Okay. I'm sorry.Q. Let me be clear. | 10 | A. I did not. |
| 12 | · · | 12 | |
| 13 | • | 13 | Q. I'm going to hand you a copy of what's going to be marked as or has been marked as Gillies |
| ١ | Q. So the record is clear, Mr. Davis states, quote, reference is made to Mallinckrodt standard | | Exhibit 16. |
| 14 | operating procedure SOPC-S comp 3.0 | 15 | [Exhibit Mallinckrodt-Gillies-016 |
| 16 | A. Okay. Thank you. | 16 | marked for identification.] |
| 17 | Q entitled identification and review of | 17 | Q. And I just have a few questions about |
| 18 | peculiar orders. | | this. |
| 19 | A. Okay. | 19 | For the record, this is a document ending |
| 20 | Q. Did I read that correctly? | 20 | in Bates 264275, and it is the global controlled |
| 21 | A. Yes. | | substance compliance procedure as of January 4th, 2011. |
| 22 | Q. Is it fair to say that Mr. Davis is | 22 | And you see, Mr. Gillies, that this is |
| | referencing the standard operating procedure referenced | | continues to be another version of the of |
| | as part of Exhibit 14 that we just looked at a moment | | Mallinckrodt's SOM policy; is that fair to say? |
| | | | Manne Rode's Boll policy, is that full to say. |
| | Page 171 | | Page 173 |
| 1 | ago? | 1 | A. Yes. |
| 2 | A. Yes. | 2 | Q. And it's dated January 4th, 2011? |
| 3 | Q. And you understood both in your review of | 3 | A. Yes. |
| | this memorandum and in your preparations that Mr. Davis | 4 | Q. And for this particular draft or version, |
| | did indeed review certain SOM procedures and policies | | the peculiar order definition remains the same as the |
| | of Mallinckrodt; correct? | | previous version we looked at; correct? |
| 7 | A. Correct. | 7 | A. Correct. |
| 8 | Q. And this memorandum reflects his review | 8 | Q. So just so the record is clear, as of |
| 9 | and advice to Karen Harper regarding this particular | 9 | January of 2011, the peculiar order algorithm utilized |
| 10 | SOM policy; correct? | ١ | by Mallinckrodt was a criteria reflecting |
| 11 | MR. O'CONNOR: Objection to form. | 11 | the average amount of the product ordered during the |
| 12 | A. Yes. | 12 | previous 12 months by DEA reporting class; correct? |
| | DV MD VO. | | |
| 13 | BY MR. KO: | 13 | A. Yes. |
| 14 | Q. That's all the questions I have on that. | 14 | Q. You can set that one aside. |
| 14 15 | Q. That's all the questions I have on that. Set that one aside. | 14 15 | Q. You can set that one aside.I'm now going to hand you a copy of what |
| 14 15 16 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding | 14 15 16 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the |
| 14 15 16 17 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding of how long Mr. Davis was retained as an outside | 14 15 16 17 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the record is a cover e-mail from April 7th, 2011, ending |
| 14 15 16 17 18 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding of how long Mr. Davis was retained as an outside consultant for Mallinckrodt? | 14 15 16 17 18 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the record is a cover e-mail from April 7th, 2011, ending in Bates 264199. |
| 14 15 16 17 18 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding of how long Mr. Davis was retained as an outside consultant for Mallinckrodt? A. A short time, was my recollection, and his | 14 15 16 17 18 19 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the record is a cover e-mail from April 7th, 2011, ending in Bates 264199. [Exhibit Mallinckrodt-Gillies-017 |
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| 14 15 16 17 18 19 20 21 22 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding of how long Mr. Davis was retained as an outside consultant for Mallinckrodt? A. A short time, was my recollection, and his contract was not renewed. Q. And do you I'm trying to get an understanding of what you mean by short time. Do you | 14 15 16 17 18 19 20 21 22 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the record is a cover e-mail from April 7th, 2011, ending in Bates 264199. [Exhibit Mallinckrodt-Gillies-017 marked for identification.] Q. And an attachment ending in 264199. MR. KO: Here you go. You can have it. |
| 14 15 16 17 18 19 20 21 22 23 | Q. That's all the questions I have on that. Set that one aside. By the way, do you have any understanding of how long Mr. Davis was retained as an outside consultant for Mallinckrodt? A. A short time, was my recollection, and his contract was not renewed. Q. And do you I'm trying to get an | 14 15 16 17 18 19 20 21 | Q. You can set that one aside. I'm now going to hand you a copy of what will be marked as Gillies Exhibit 17, which for the record is a cover e-mail from April 7th, 2011, ending in Bates 264199. [Exhibit Mallinckrodt-Gillies-017 marked for identification.] Q. And an attachment ending in 264199. |

Page 174 1 BY MR. KO: 1 revisions to this particular document; correct? 2 Q. Just a few questions on this as well. A. She's asking her to clean up the format. Q. Okay. Fair enough. ³ Turn to the attachment. A. Yeah, I'm sorry. What did you say the A. Okay. number on the attachment was? Q. In the April -- in the corresponding April 7th e-mail from Eileen to Karen --6 Q. The attachment ended in Bates 264200. 7 A. Okay. Thanks. Α. Okav. 8 Q. I may have misspoke. Yeah, you're right. 8 -- Eileen appears to make some additions to the document; is that correct? The cover e-mail ends in 199. 10 A. Okay. 10 A. I'm sorry. I didn't read that part. 11 So -- yes. 11 Q. The attachment ends in 200. 12 A. I just wanted to make sure we were looking 12 Q. So does this e-mail reflect that the 13 at the same document. 13 attachment ending in Bates 200 is a draft written 14 Q. Yeah. Thank you for that clarification. policy of Mallinckrodt's SOM program? 15 So this is another version or draft of A. Again, it doesn't say draft on here. So 16 Mallinckrodt's SOM written policy dated March 28th, 16 she could have been making some enhancements to an 2011; correct? 17 actual policy. 17 18 A. Yes. 18 Q. I understand that. But as it relates to 19 Q. And by this, just so the record is clear, this particular -- I have a specific question with I'm referring to the document ending in Bates 200. respect to this policy --21 And turning to the next page, again you 21 A. Okay. 22 see a definition of peculiar order; correct? Q. -- that's attached to this particular 23 A. Yes. 23 e-mail. 24 24 And the definition of a peculiar order A. Right. Page 175 Page 177 1 remains unchanged from the prior two versions; correct? Q. This document that ends in Bates 200 2 ² appears to be a draft SOM policy of Mallinckrodt; A. Correct. Q. So as of March 28th, 2011, the formula 3 correct? 4 utilized by Mallinckrodt to determine whether or not an A. I don't know that. 5 order was peculiar was to determine whether or not the Q. So I'll represent to you that this the average amount of product 6 order was 6 attachment that is referenced in Eileen's e-mail to 7 ordered during the previous 12 months by DEA reporting ⁷ Karen is in fact the attachment that's part of this class: correct? 8 e-mail. 9 A. Correct. A. Okay. 10 Q. And going back to the cover e-mail ending 10 Q. And so with that representation, would you 11 agree with me that the policy dated March 28th, 2011, in 199, I believe there's a reference made to a --12 MR. KO: Thanks, Andrew. ending in dash 200 is a draft version of Mallinckrodt's 13 BY MR. KO: 13 SOM policy, or is it your belief -- or you can't answer Q. Well, let me ask it this way. So there's 14 that question? 15 a -- this is an e-mail exchange between Eileen 15 A. Well, again, I'll stick with my original 16 Spaulding and Karen Harper from the March and April of answer, which is no, it could be revisions to an 17 2011 time period; correct? existing policy. So I don't know that to be a draft. 18 A. Yes. I guess that's what I'm saying. 19 Q. And is it fair to say that Karen is asking 19 So if I knew this to be a draft, fine, but 20 Eileen to make some revisions to this particular I don't know this to be a draft, so these could be policy? Correct? revisions she made to an existing policy. 21 22 A. Could you repeat your question? 22 Q. Fair enough. Q. Sure. In the underlying e-mail dated 23 A. Okay.

24

24 March 30th, 2011, Karen is asking Eileen to make some

Do you know -- have you seen -- in any of

- 1 the review of your documents in preparation for this
- 2 deposition, have you ever seen an SOM written policy in
- 3 this time period of March 28th, 2011, that reflects a
- 4 formal written policy of Mallinckrodt?
- 5 MR. O'CONNOR: Objection to form.
- 6 A. This may have been one of the documents
- 7 that I reviewed, and it appears to me to be a formal
- 8 written policy.
- 9 BY MR. KO:
- Q. But in the cover e-mail, there are some
- 11 changes being made; is that fair?
- 12 A. That's fair.
- Q. And so all I'm asking is that for this
- 14 particular document ending in dash 200, that appears to
- be a draft policy because Eileen and Karen are making
- 16 some slight changes to it; is that correct?
- A. No, that's not my testimony. My testimony
- 18 is that I don't know this to be a draft, and this could
- 19 be a formal policy in play that has some revisions made
- 20 to it. That's --
- Q. Sure. Fair enough. Do you recall seeing
- 22 a formal policy during the March 2011 time period
- 23 regarding Mallinckrodt's SOM program?
- A. Again, I may have reviewed this policy.

A. Yes.

1

- Q. And it indicates that she is senior
- 3 manager of controlled substance compliance; correct?

Page 180

Page 181

- A. Yes
- Q. And earlier I know you had said that you
- 6 were unaware of whether or not there was controlled
- 7 substance compliance group. Does this refresh your
- 8 recollection at all that there was in fact such a group
- 9 at Mallinckrodt?
 - A. So I'm going to take this that the DEA
- compliance and the controlled substance compliance are
- 12 the same.

10

- Q. Okay. Fair enough. So is it your
- 14 understanding that there were certain times at
- 15 Mallinckrodt where the DEA compliance group was also
- referred to as the controlled substance compliance
- 17 group?
- A. So my recollection is I only knew that
- 19 group as DEA compliance.
- Q. And you have no recollection of whether or
- 21 not there was an actual or formal group called the
- 22 controlled substance compliance group at Mallinckrodt?
- MR. O'CONNOR: Objection to form.
- A. I'm unaware of that, and from looking at

Page 179

- Q. And is it your testimony that Mallinckrodt
- 2 did in fact have a formal written policy as of 2011
- 3 regarding its SOM program?
- 4 MR. O'CONNOR: Objection to form.
- 5 A. That's my understanding.
- 6 BY MR. KO:
- 7 Q. And who informed you that the particular
- 8 version that you may have looked at was in fact the
- 9 formal policy regarding Mallinckrodt's SOM program?
- 10 A. I didn't say anybody did. I said that I
- 11 may have reviewed this during that period and made that
- 12 conclusion on my own.
- Q. I see. We can set that one aside.
- 14 A. Okay.
- Q. We will now go over what's been marked as
- 16 Gillies Exhibit 18. Excuse me.
- 17 [Exhibit Mallinckrodt-Gillies-018
- marked for identification.]
- Q. And for the record, this ends in Bates
- 20 259166, and this is titled Mallinckrodt suspicious
- 21 order monitoring procedure dated August 8th, 2011.
- On this particular document, the
- 23 originator continues to be Karen Harper. Do you see
- 24 that?

- 1 this title I believe them to be the same.
- 2 BY MR. KO:
- Q. And do you have any understanding -- or
- 4 did you review any documents that predate August 2011
- 5 that may have referenced a controlled substance
- 6 compliance group?
- A. So some of the previous documents that you
- 8 showed me had that same title -- or that same name
- 9 after Karen's title, so the answer to your question is
- 10 yes.

- Q. But -- and your testimony is that you
- 12 believe them to be essentially synonymous; is that
- 13 correct?
- 14 A. That's correct.
- Q. And for this particular document, if you
- 16 look at the top of Page 2, the definition of peculiar
- 17 order is again set forth. Do you see that?
- 18 A. Yes.
- Q. And as with the previous three versions
- 20 that we have looked at, the definition of a peculiar
- 21 order remains unchanged. Is that accurate?
- 22 A. Yes.
- Q. So as of August 8th, 2011, so the record
- 24 is clear, Mallinckrodt utilized a peculiar order

| | 3 1 | | |
|--|---|--|---|
| | Page 182 | | Page 184 |
| 1 | algorithm which identified a peculiar order as one | 1 | suspicious orders. Is that fair to say? |
| 2 | being an order that was the average amount | 2 | A. Yes. |
| 3 | ³ of product ordered by or ordered during the previous | 3 | Q. And the change is it accurate to say |
| 4 | 12 months by DEA reporting class; correct? | 4 | that this document reflects a description of how |
| Ę | A. Yes. | 5 | Mallinckrodt is moving from a peculiar order |
| 1 | Q. Set that one aside. Move on to what's | 6 | classification or system to an unusual order system? |
| 7 | going to be marked as Gillies Exhibit 19. And this | 7 | MR. O'CONNOR: Objection to form. |
| 8 | document ends in Bates 571916. | 8 | A. Yes. |
| و | Exhibit Mallinckrodt-Gillies-019 | 9 | BY MR. KO: |
| 10 | marked for identification.] | 10 | Q. And in this document, there's an |
| 11 | Q. So earlier today we had discussed the fact | 11 | indication that, quote, target date for go live for the |
| 12 | that Mallinckrodt had a two-tier or sometimes | 12 | unusual order detection system is March 1st, 2012. |
| 13 | three-tier structure in identifying suspicious orders; | 13 | Did I read that correctly? |
| 14 | correct? | 14 | A. Yes. |
| 15 | A. Correct. | 15 | Q. Do you have any reason to dispute that the |
| 16 | Q. And in all of the documents that we just | 16 | unusual order detection system was in fact implemented |
| 17 | looked at and all the policies, the definition of a | 17 | at some point in early 2012? |
| 18 | | 18 | A. I think that's accurate. |
| 19 | dentifying a suspicious order included an initial | 19 | Q. And can you explain to the court what the |
| 20 | | 20 | difference is between or can you explain to the |
| 21 | - correct? | 21 | court why there was a change made to the unusual order |
| 22 | A. Correct. | | system? |
| 23 | Q. And at some point in time Mallinckrodt | 23 | MR. O'CONNOR: Objection to form. |
| 24 | moved to a definition or strike that. | 24 | A. No. |
| | | | |
| | D 102 | | D 107 |
| | Page 183 | | Page 185 |
| 1 | At some point in time Mallinckrodt removed | | BY MR. KO: |
| 2 | At some point in time Mallinckrodt removed the definition of a peculiar order for purposes of | 1 2 | BY MR. KO: Q. You don't have an understanding of why |
| 3 | At some point in time Mallinckrodt removed the definition of a peculiar order for purposes of identifying a suspicious order; is that accurate? | 2 | BY MR. KO: Q. You don't have an understanding of why Mallinckrodt changed from a peculiar order system to an |
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| | Page 186 | | Page 188 |
| | And then Tier 3 were new SKUs outside of | 1 | algorithm designed to restrict increases over time that |
| | 2 those products, and that was used for a short time and | 2 | will apply to orders from all other customers of SKUs |
| | 3 then incorporated into the other two tiers. | 3 | identified by DEA as particularly subject to diversion |
| | Q. Okay. And approximately how long was this | 4 | and abuse. |
| | 5 three-tier system utilized? | 5 | Did I read that correctly? |
| | A. I believe approximately three to six | 6 | A. Yes. |
| | 7 months, maybe. | 7 | Q. Do you know whether or not that particular |
| | Q. In the 2012 time period? | 8 | tier was ever utilized in connection with |
| | 9 A. Yes. | 9 | Mallinckrodt's SOM program? |
| 1 | Q. And turning back to this document, there | 10 | A. I mean, the tier continues right on the |
| 1 | actually is a reference made underneath the general | 11 | second page. So if I could just |
| 1 | 2 section we were just looking at about the tiers. Do | 12 | Q. Fair enough. And take your time to read |
| 1 | | 13 | that. I'll let you review that. |
| 1 | 4 A. Yes. | 14 | A. All right, thanks. Okay. So can you |
| 1 | Q. And then there's Tier 2 and 3 later on? | 15 | repeat your question now? |
| 1 | 6 A. Could have read this. Right | 16 | Q. Sure. Was the description contained in |
| 1 | | 17 | this particular exhibit regarding Tier 2 ever utilized |
| 1 | | 18 | or memorialized in a Mallinckrodt SOM policy? |
| 1 | | 19 | MR. O'CONNOR: Objection to form. |
| 2 | • | 20 | A. I believe, yes. |
| 2 | Q. In other words, Mallinckrodt was trying to | 21 | BY MR. KO: |
| 2 | | 22 | Q. And approximately when was that? |
| 2 | | 23 | A. The same time frame. |
| 2 | • | 24 | Q. And was it |
| | Page 187 | | Page 189 |
| | MR. O'CONNOR: Objection to form. | 1 | A. Oh. December 2011. Yeah, so again, the |
| | A. Correct. | 2 | date on this is December 2011, and my understanding is |
| | 3 BY MR. KO: | 3 | that this procedure went into play in March of 2012. |
| | Q. And in particular strike that. | 4 | Q. And in fact, the procedure outlined here |
| | In addition, Mallinckrodt was also trying | 5 | with respect to Tier 2 and Tier 3 is it your |
| | 6 to design an SOM program that was specifically focused | 6 | testimony that those tiers were in fact utilized as of |
| | 7 on ABC, Cardinal, McKesson, and H.D. Smith; correct? | 7 | March of 2012? |
| | MR. O'CONNOR: Objection to form. | 8 | A. Yes. |
| | 9 A. Yes. | 9 | Q. You can set that document aside. I'm |
| 1 | 0 BY MR. KO: | 10 | going to hand you what's just been marked as Gillies |
| 1 | Q. And earlier you had said the big three | 11 | Exhibit 20. |
| 1 | 2 plus H.D. Smith. These are the four distributors that | 12 | [Exhibit Mallinckrodt-Gillies-020 |
| 1 | were customers of Mallinckrodt that it was focusing on | 13 | marked for identification.] |
| 1 | 4 for purposes of its SOM program at this time; correct? | 14 | Q. And this document ends in Bates 2357607, |
| 1 | 5 A. Correct. | 15 | and it is titled identification and an investigation of |
| 1 | 6 MR. O'CONNOR: Objection to form. | 16 | unusual orders of controlled substances and reports of |
| 1 | 7 BY MR. KO: | 17 | suspicious orders of controlled substances. Do you see |
| 1 | Q. And in your description that you gave a | 18 | that? |
| 1 | | 19 | A. Yes. |
| 2 | 0 little different than what's referred to in this | 20 | Q. There's no date on this particular |
| 1 | | 1 | 1 . 1 . 4 |

24 indicates that Tier 2 is, quote, an enhanced standard

Q. And here -- in particular, this document

21 particular document.

A. Okay.

22

21 document, but there is a reference in the top

23 that?

A. I do.

24

22 right-hand corner that says that it's new. Do you see

Q. And I know you said earlier that you've reviewed some SOM policies in preparation for this deposition.

4 Do you recall reviewing this SOM policy?

- A. I believe I did.
- 6 Q. And is this the policy -- so a moment ago
- ⁷ we were talking about the unusual order system, the
- 8 target date for that system to go live as of March of
- 9 2012.

5

- Does this particular policy reflect the
- 11 new revised system that Mallinckrodt implemented at
- 12 that time?
- MR. O'CONNOR: Objection to form.
- 14 A. I believe it did.
- 15 BY MR. KO:
- Q. And in this particular document there are
- 17 definitions made to unusual order and suspicious order.
- 18 Do you see that?
- 19 A. Yes.
- Q. And similar to some of the prior policies
- 21 that we were discussing earlier today that first
- 22 determined whether an order was peculiar and then
- 23 subsequently analyzed for whether or not the order was
- 24 suspicious, here we have a multitiered approach as well

- 1 A. That's my understanding.
 - Q. We can set that one aside. I'm going to
 - 3 hand you now a copy of what will be marked as Gillies

Page 192

Page 193

- 4 Exhibit 21, which is a cover e-mail from Eileen to
- 5 Karen Harper dated September 20th, 2012, together with
- 6 an attachment that begins on Bates 7728782.
 - [Exhibit Mallinckrodt-Gillies-021
- 8 marked for identification.]
- 9 Q. So before -- we can look at the cover
- 0 e-mail in a moment, but looking at the policy itself,
- this appears to be another written policy of
- 12 Mallinckrodt's SOM program; is that correct?
- 13 A. Yes.
- Q. And there's no date, similar to the one we
- 15 just looked at, but the cover e-mail for this
- 16 particular attachment is from September of 2012;
- 17 correct?
- 18 A. Yes.
- Q. So in September of 2012 Mallinckrodt is
- making revisions to its SOM policy; correct?
- 21 A. Correct.
- Q. And in the definitions section, there
- 23 is -- you see that there is a reference to Tiers 1 and
- 24 2 but not Tier 3?

Page 191

- 1 that distinguishes between an unusual order and a
- 2 suspicious order; correct?
- 3 MR. O'CONNOR: Objection to form.
- 4 A. Yes.
- 5 BY MR. KO:
- 6 Q. And an unusual order is one -- well, let
- 7 me read it so that the record is clear.
- 8 An unusual order. An order received by
- 9 Mallinckrodt directly from a customer for a Schedule II
- 10 through V controlled substance product which exceeds
- 11 the internal limit set by the application of the
- 12 three-tiered system of specifically-created algorithms
- 13 defined in this policy.
- Did I read that correctly?
- 15 A. Yes.
- Q. And that three-tiered system is defined
- 17 later on in 4.3 through 4.5 of the definitions,
- 18 correct, on the first page?
- 19 A. Oh. Okay. Yes.
- Q. So in other words, if through analysis of
- 21 Tiers 1 through 3 an order is triggered as being
- ²² unusual, it would warrant further investigation to
- 23 determine whether or not an order was suspicious
- 24 sufficient to notify the DEA; correct?

- A. Correct.
- Q. And so earlier when we had discussed the
- 3 period of time in which there was a three-tiered
- 4 structure and it moved back to a two-tiered structure,
- 5 is it your recollection that by September of 2012
- 6 Mallinckrodt had a two-tiered structure to identify
- 7 whether an order was unusual?
- 8 A. Yes.
- 9 Q. And so is it fair to say from March of
- 10 2012 through September of 2012, Mallinckrodt utilized a
- 11 three-tiered structure to analyze whether an order was
- 12 unusual?
- 13 A. Yes.
- Q. And after moving back to two tiers to
- define an unusual order, has there been any point in
- 16 time from 2012 to present in which Mallinckrodt
- 17 utilized anything other than a two-tiered structure to
- 18 determine whether or not an order was unusual?
- MR. O'CONNOR: Objection to form.
- A. Not that I'm aware of.
- 21 BY MR. KO:
- Q. And if we examine the -- this particular
- 23 draft, there is no reference made to suspicious order.
- 24 Do you see that?



- 1 A. Well, I mean, under 4.1 it says unusual
- 2 orders will be reported to DEA upon discovery as
- 3 suspicious orders in accordance with the CFR.
- Q. Okay. Fair enough. I guess I meant to
- 5 say in the prior version there was a clear definition
- 6 of an unusual order and a clear definition of
- ⁷ suspicious order; correct?
- 8 A. Okay. Yes.
- Q. And in this version the definition for
- suspicious order is removed; correct? 10
- 11 MR. O'CONNOR: Objection to form.
- 12 A. Correct. I do not see that definition.
- 13 BY MR. KO:
- 14 Q. And in the two-tiered system that now
- 15 comprises the unusual orders algorithm, do you have an
- 16 understanding of why that change was made from three
- 17 tiers back down to two?
- 18 A. It was my understanding that the third
- 19 tier was incorporated into the Tier 2.
- 20 Q. And so in other words -- well, how was it
- incorporated?
- 22 A. It's my understanding that there were few,
- 23 if any, that fell into that Tier 3 category, and that
- 24 if it were to -- if that category or that instance were

- 1 made to both the average number of orders and the
 - 2 average number of volume. Do you see that?
 - - Q. So in order to trigger this algorithm
 - 5 referenced in Tier 2, did the order have to be both
 - the average number of orders and
 - the average of volume in order to trigger the
 - unusual orders algorithm set forth in this policy? MR. O'CONNOR: Objection to form. 9
 - 10
 - A. So the way I read 4.3, yes.
 - 11 BY MR. KO:
 - 12 Q. And prior -- it's fair to say that prior
 - 13 to two thousand -- September of 2012, Mallinckrodt did
 - not utilize or did not investigate into the total
 - average volume of a product that was ordered during a
 - prior time period?
 - 17 MR. O'CONNOR: Objection to form.
 - 18 A. I'm not aware of that.
 - BY MR. KO:
- 20 Q. Did you ever see reference to any written
- SOM policy prior to September of 2012 that incorporated
- historical overview of the average volume of a product
- ordered by a particular customer?
- MR. O'CONNOR: Objection to form.

- 1 to happen, it would now be picked up by Tier 2.
- Q. I see. And so when you say that there
- ³ were few, if any, that fell into the Tier 3 category,
- 4 that was the Tier 3 category that was in existence from
- 5 March of 2012 through September of 2012?
- A. That's right. So this would have been an 6
- 7 enhancement to that based on the experience over the
- previous six months.
- Q. And with respect to Tier 2, the standard
- 10 algorithm is referenced as follows. the average
- 11 number of orders of a product during the previous 18
- 12 months by the customer, and, B, the average volume
- 13 of product ordered during the previous 18 months by the
- 14 customer.
- 15 Did I read that correctly?
- A. Yes. 16
- 17 O. And so what's different about this
- particular algorithm is that there's an increase in the
- 19 time period; is that correct?
- 20 A. Yes.
- 21 Q. From 12 months to 18 months?
- 2.2 Correct.
- 23 And there's -- what I want to understand
- 24 and make sure I have correct is that there's reference

- A. Not that I can recall.
- ² BY MR. KO:
- Q. And in this document, the Tier 1 sets
- 4 forth a tier devoted to oxy 15s and oxy 30s by certain

Page 197

- distributors; correct?
- A. Yes.
- 7 Q. And --
- A. Similar to the previous.
- Q. Right. And there was -- well, explain to
- the court why it was important for Mallinckrodt to
- focus on oxy 15s and oxy 30s and set that apart for
- purposes of its SOM policy.
- 13 MR. O'CONNOR: Objection to form.
- 14 A. These were our largest customers.
- 15 BY MR. KO:
- Q. And by largest customers you mean ABC, 16
 - McKesson, Cardinal, and H.D. Smith?
 - A. Yes.

18

23

- 19 Q. And what about with respect to oxy 15s and
- 20 oxy 30s? Were -- was that the primary -- or did those
- prescription opioids reflect the majority of drugs
- manufactured by Mallinckrodt during this time?
 - A. I don't know that to be the case.
 - Q. Is it accurate to state that following the

Page 198 1 August 2011 meeting that we had discussed before with 1 as particularly subject to diversion and abuse, end ² the DEA, the DEA was particularly concerned about 2 quote. 3 diversion of oxy 15s and oxy 30s of -- manufactured by 3 Did I read that correctly? 4 Mallinckrodt; correct? Yes. 5 MR. O'CONNOR: Objection to form. Q. Were there any other drugs that the --6 prior to 2012 that the DEA had informed Mallinckrodt of 6 A. I don't know that that characterizes the 7 meeting accurately. From my recollection, they were 7 being subject to diversion and abuse? 8 telling us that they were concerned about oxy 15s and MR. O'CONNOR: Objection to form. A. Not that I'm aware of. 9 oxy 30s, and I don't know that they qualified it saying 10 that it was just Mallinckrodt oxy 15s or 30s. 10 BY MR. KO: 11 BY MR. KO: 11 Q. Do you know whether or not the DEA had 12 Q. Fair enough. Mallinckrodt manufactures informed Mallinckrodt that the methadone that it was 13 oxy 15s and oxy 30s; correct? manufacturing was subject to diversion and abuse? 14 A. That's correct. 14 MR. O'CONNOR: Objection to form. 15 Q. And Mallinckrodt has been manufacturing 15 A. No. 16 those products for -- since at least the mid-2000s; 16 BY MR. KO: correct? 17 17 Q. You have no knowledge of that, or you 18 A. That's my understanding. 18 believe --19 19 A. I'm not aware of that. Q. And when you said a moment ago that --20 when you were talking about your recollection of what 20 Q. You're not aware of that? Okay. In the DEA said, that was through your review of addition to oxy 15s and oxy 30s, Mallinckrodt 22 documents; correct? manufactured other prescription opioids; correct? 23 23 A. Correct. A. Correct. 24 Q. In other words, I mean, you weren't at the 24 Q. Including from the hydrocodone and Page 199 Page 201 1 hydromorphone molecules? 1 meeting? 2 2 A. I was not. A. Yes. 3 Q. That predates your --Q. And do you recall prior to 2012 whether or 4 not the DEA had any communications with Mallinckrodt 4 A. It does. 5 -- employment with Mallinckrodt; correct? 5 regarding whether or not these products were subject to diversion and abuse? 6 A. Correct. 7 A. No. Q. And so going back to this document, there 8 is obviously a specific reference made to oxy 15s and Q. No, you don't have any recollection of oxy 30s; correct? those communications? 9 10 A. Yes. 10 A. I do not. Yes. 11 Q. And so why was it the case that 11 Q. But you don't know whether or not they 12 Mallinckrodt had designated a specific tier in its SOM happened one way or the other? policy for oxy 15s and oxy 30s? 13 A. I have no recollection of that being 14 A. As we had previously in the policies, I 14 discussed --15 believe it came from the discussion with DEA. 15 Q. Got it. Q. So as a result of DEA's -- is it fair to 16 16 -- prior to this time frame. say as a result of DEA's increased scrutiny on oxy 15s 17 Q. And what about following September 2012? and oxy 30s, Mallinckrodt decided to designate those Did Mallinckrodt have any discussions with DEA particular drugs as part of its SOM written policy? regarding the diversion and abuse potential of any 19 20 MR. O'CONNOR: Objection to form. hydrocodone or hydromorphone products? 21 21 A. I became aware of that.

2.2

23

24

Q. And this particular document indicates

24 that, quote, these products have been identified by DEA

A. As a separate tier, yes.

22 BY MR. KO:

Q. During what time period?

A. Post-September 2012 time frame.

And when approximately?

Page 202 1 A. Sometime after September of 2012. So Q. And do you recall for what time period 2 October, November time frame. Late 2012. 2 these discussions covered? 3 Q. So shortly after? So my recollection is late 2012 into early Shortly after. Yeah. 4 2013. Q. I see. So fair to say that in the fall of 5 Q. And do you recall any discussions with the 6 2012, Mallinckrodt communicated with the DEA regarding 6 DEA regarding the abuse and diversion potential of 7 the diversion and abuse potential of its hydrocodone 7 hydrocodone and hydromorphone following early 2013? and hydromorphone products? A. I have no recollection of any specific A. Again, not -- it wasn't Mallinckrodt. It discussions on that. Q. Here is a copy of what's going to be 10 was just you need to start looking at hydrocodone too. 10 11 So they didn't say we have a problem with marked as Gillies Exhibit 22. 11 12 Mallinckrodt hydrocodone; it's we're seeing a problem 12 [Exhibit Mallinckrodt-Gillies-022 13 with hydrocodone now too. 13 marked for identification.] 14 Q. I understand. 14 Q. And for the record, this document ends in A. Okay. I just want to make sure I'm 15 Bates 7476261, and it is entitled identification understanding your question, because -investigation reports of controlled substances 17 Q. Sure. And that's a fair clarification of suspicious orders, effective date October 18th, 2012. 18 the record. Do you recall reviewing this document in 19 A. Okay. preparation for this deposition today? 20 A. No. 20 Q. Mallinckrodt did in fact manufacture 21 certain hydrocodone and hydromorphone products; 21 Q. For this particular -- let me take a step 22 back. 22 correct? 23 23 A. Correct. Did you review any written policies 24 And it's your testimony today -- is it an 24 regarding Mallinckrodt's SOM procedure in preparation Page 203 Page 205 1 accurate reflection of your testimony that Mallinckrodt 1 for your deposition today? 2 communicated with the DEA regarding the abuse and A. I believe I did. 3 diversion potential of hydrocodone and hydromorphone O. Which ones? 4 products in general? MR. O'CONNOR: I'm going to object. 5 A. Yes. 5 Again, we're not going to get into the specific 6 selection of documents on the basis of work product and 6 Q. You can set that one aside. 7 And by the way, with respect to ⁷ attorney-client privilege. 8 hydrocodone and hydromorphone, did those discussions BY MR. KO: about the abuse and diversion potential of those Q. Did review of those documents help refresh 10 products -- how long did they last? your recollection at all as to Mallinckrodt's SOM 11 MR. O'CONNOR: Objection to form. policies over time? A. I don't know what you mean by the timing MR. O'CONNOR: Objection to form. 13 of that. You mean like a five-minute meeting or over a 13 Objection to the extent you're asking him to confirm 14 certain amount of time? which documents. 15 BY MR. KO: 15 BY MR. KO: Q. Yeah. 16 16 Q. And I'm not. I'm simply asking whether or 17 A. So I'm sorry. not review of certain SOM written policies that you 18 Q. Fair enough. Did you -- when you began claim you have reviewed help refresh your recollection 19 having discussions with the DEA about the hydro -regarding SO -- Mallinckrodt's SOM system. 20 about the abuse and diversion potential of 20 A. 21 hydromorphone and hydrocodone, how -- do you recall how 21 Q. And which specific documents did you

22 review?

24 Instruct the witness not to answer.

23

A. Several, at least.

23 topic?

24

22 many meetings with the DEA Mallinckrodt had on this

MR. O'CONNOR: Again, same objection.

- MR. KO: Okay. Well, and I'll note for
- ² the record that that's an improper instruction, because
- ³ anything that refresh the witness's recollection in
- 4 terms of preparing for this deposition certainly is not
- ⁵ subject to the privilege.
- 6 MR. O'CONNOR: We can address that issue
- 7 later.
- 8 BY MR. KO:
- ⁹ Q. So just so the record is clear, Mr.
- 10 Gillies, you did review specific written policies
- 11 regarding Mallinckrodt's SOM program; correct?
- 12 A. Yes.
- Q. And do you recall approximately how many
- 14 you reviewed?
- 15 A. I do not.
- O. Was it more than five?
- 17 A. No.
- Q. So you reviewed -- was it more than three?
- A. I don't know how many I did, but I don't
- 20 believe it was more than five.
- Q. And for what time period did those
- 22 policies span?
- A. Yeah. I don't recall.
- Q. But you reviewed no more than five written

- ¹ of the questions that I want to ask about this.
- This is -- this document reflects that you
- ³ are part of the SOM leadership team; correct?
 - A. Yes.
- Q. And was this the first document that you
- ⁶ became -- or the first SOM policy that you became
- ⁷ involved in after you joined Mallinckrodt?
- MR. O'CONNOR: Objection to form.
- 9 A. I don't think so.
- 10 BY MR. KO:

11

13

14

- Q. So prior to this date you had reviewed
- 12 some other drafts or policies; correct?
 - A. Yes.
 - Q. And for this particular version of the SOM
- policy, there is a definition of suspicious order. Do
- ¹⁶ you see that -- in 4.1?
- 17 A. Yes.
- Q. And there's no -- the definition of an
- unusual order is removed; correct?
- 20 A. Yes.
- MR. O'CONNOR: Objection to form.
- 22 BY MR. KO:
- Q. But regardless of the names of the
- ²⁴ definition, the two-tiered structure for determining

Page 209

Page 207

- 1 policies for a time period you don't recall, is that
- ² accurate, in connection with preparing for this
- ³ deposition?
- 4 A. Correct.
- ⁵ Q. And you don't recall reviewing -- as we
- 6 discussed earlier, you don't recall reviewing this
- ⁷ particular one; correct?
- 8 A. During my preparation for this deposition?
- 9 Q. Yes.
- 10 A. No.
- Q. How about outside of the preparation for
- 12 the deposition, do you recall ever seeing any
- 13 Mallinckrodt written SOM policies?
- 14 A. Yes.
- O. Which ones?
- A. I recall this one.
- Q. You do recall reviewing this one, then,
- 18 but not --
- A. But now I got the clarification, it wasn't
- ²⁰ for this purpose.
- Q. And you recall --
- A. And I was employed by Mallinckrodt at this
- 23 time.
- Q. Okay. We'll get -- that segues into a few

- 1 whether or not an order may potentially be suspicious
- ² remains the same from the prior version we looked at;
- 3 correct?
- 4 A. Yes.
- 5 Q. And going back to the SOM leadership team,
- 6 we see that it's comprised of Don Lohman, you, John
- ⁷ Gillies, Gail Tetzlaff, who you I believe referred to
- 8 before, and Karen Harper.
- 9 A. Correct.
- Q. Do you see that?
- 11 A. Uh-huh.
- Q. Was that the same leadership structure
- 13 that was in place when you joined Mallinckrodt in June
- 14 of 2012?
- MR. O'CONNOR: Objection to form.
- 16 A. Yes.
- 17 BY MR. KO:
- Q. And I believe you -- again, you referred
- 19 to Gail before, and you referred to the SOM leadership
- team, but I want to understand clearly whether or not
- 21 this -- well, strike that.
- Since 2012 to present, has the composition
- 23 of the SOM leadership team changed at all?
- 24 A. Yes.

Page 210 Page 212 A. Correct. 1 Q. In what way has it changed? 1 2 2 A. I believe we have an additional member or And why was this change made? A. An enhancement to the program. So we had 3 two to the leadership team. Q. And who are they? 4 the at one point, then we had the , and through 5 A. I believe Jason Tilly is part of the 5 time we enhanced the program again, and it's always 6 leadership team, and I believe there's one other party. 6 undergoing review, and at this point a change was made ⁷ But I -- sorry. I can't remember their name. 8 Q. Okay. Fair enough. And do you recall Q. And it's my understanding that the -- is when Mr. Tilly was added to the SOM leadership team? it the case that the 10 A. I don't recall the time frame. order in volume is the current system 11 in place as well? 11 Q. And how about the other individual who you 12 12 don't recall? Do you have any understanding of when A. That's correct. 13 she or he was added to the team? Q. So is it accurate to say that from 14 A. I believe we added another member sometime 14 November 2012 to present the algorithm to detect 15 in late 2018. suspicious order has not changed? 16 Q. So recently? MR. O'CONNOR: Objection to form. 17 17 A. Recently. Uh-huh. A. That's my understanding. 18 Q. So fair to say from 2012 through 2018 the 18 BY MR. KO: 19 composition of the SOM leadership team were the four 19 Q. And just so the record is clear, the -- in individuals listed here and Mr. Tilly at some point? this particular document, the special attention on oxy 21 MR. O'CONNOR: Object to form. 15s and 30s distributed by Mallinckrodt's major 22 A. Yes. customers remains to be in the policy; correct? 23 23 BY MR. KO: A. Correct. 24 Q. You can set that aside. I'm now going to 24 And in the current iteration of the SOM Page 211 Page 213 1 hand you a copy of what will be marked as -- or what 1 policy, does that Tier 1 still exist? 2 has been marked as Gillies Exhibit 23. A. In this policy? 3 [Exhibit Mallinckrodt-Gillies-023 Q. I'm sorry. 4 marked for identification.] A. I'm sorry. 5 Q. For the record, this ends in Bates Yeah, I'm sorry if I confused you. In the 6 current iteration of Mallinckrodt's SOM policy today, 6 5620500. 7 ⁷ is there still special attention given to oxy 15s and And this is a document titled 8 oxy 30s? 8 identification, investigation, and reports of controlled substances suspicious orders, effective date MR. O'CONNOR: Objection to form. 10 November 1st, 2012. Do you see that? 10 A. Yes. 11 A. Yes. 11 BY MR. KO: 12 Q. And it appears to supersede the prior Q. And is there still special attention given 13 version that we just looked at from October 18th, 2012? 13 to oxy 15s and 30s distributed by ABC, McKesson, 14 Cardinal, and H.D. Smith? 15 Q. And I just have a quick question on this 15 MR. O'CONNOR: Objection to form. 16 A. Yes. 16 document. 17 A. Uh-huh. 17 BY MR. KO: 18 Q. Here in Tier 2, there's an adjustment made 18 Q. Okay. Thank you. You can set that aside. 19 to the algorithm. Is that accurate? 19 MR. O'CONNOR: Should we take a break? 20 A. Yes. 20 MR. KO: Yeah, sure. 21 Q. And the specific adjustment that is made 21 THE VIDEOGRAPHER: We are going off the 22 is from -- down from to 22 record at 2:46 PM. 23 previous 18-month average number of orders in volume; 23 [A brief recess was taken.] 24 correct? 24 THE VIDEOGRAPHER: We are back on the

Page 214 1 record at 3:06 PM. Q. And no more than that additional one; 2 correct? ² BY MR. KO: Q. Welcome back from the break. This is the In other words, have you seen -- outside 4 of the document that postdates August 17th, 2015, have 4 home stretch, at least with respect to my questioning, ⁵ Mr. Gillies, so thank you for your patience today. ⁵ you seen any other additional SOM written policies 6 other than that version? A. Yes. 7 Q. I'm going to hand you -- or you have in MR. O'CONNOR: Objection to form. 8 front of you a copy of what's been marked as Gillies A. My recollection is that there might be two Exhibit -after this. 10 10 BY MR. KO: MS. GAFFNEY: 24. 11 Q. But you don't have an understanding of 11 BY MR. KO: 12 when those effective -- when the effective dates of Q. -- 24. And for the record, this document ends in Bates 511246, and it is titled identification, those written policies were; correct? 14 investigation, and reports of controlled substances 14 A. That's correct. ¹⁵ suspicious orders, and the effective date is August 15 Q. Now, turning to this particular document, 16 I just have a few questions on this. 16 17th, 2015, in the top right-hand corner. 17 17 A. Yes. Do you see that, Mr. Gillies? 18 [Exhibit Mallinckrodt-Gillies-024 18 Q. Here we have an identification of who is 19 marked for identification.] on the SOM team but not any names. Do you see that in 20 Section 4.5? A. Yes. 21 21 Q. Did you review this particular policy in 22 22 preparation for your deposition today? Q. And there is also an indication of a 23 23 senior data analyst being part of the team. A. No. 24 Q. And this particular document seems to Page 215 Page 217 1 indicate that it's superseding a prior version dated Q. You see that? And does that refresh your ² March 7th, 2013. Do you see that? ² recollection at all that there were, in addition to Mr. A. Yes. 3 Tilly and perhaps the other individual who you don't 4 recall was added in 2018, does that refresh your Q. Do you recall whether or not you reviewed 5 the March 7th, 2013, SOM policy? 5 recollection as to an additional member of the SOM team A. I don't recall as we sit here. 6 as of 2015? 6 7 A. Yes. Q. And do you know whether or not 8 Mallinckrodt's current SOM policy is -- well, strike Q. And who was this particular individual? 9 that. A. Jen Buist. 10 Do you have any understanding of whether 10 Q. And she currently is still with 11 or not this version that we're looking at is 11 Mallinckrodt; correct? 12 Mallinckrodt's current SOM written policy? A. No. 13 13 A. I do not. Q. Did she recently leave Mallinckrodt? 14 Q. Do you know -- have you seen recently 14 Mallinckrodt's written SOM policy? Q. When did she leave Mallinckrodt? A. I believe I've seen one more recent than 16 A. Several years ago. 16 17 ¹⁷ this. Q. Do you have an approximate time -- do you 18 Q. And do you know what approximate effective have a general understanding of the approximate time 19 date that particular document has? period in which she left? 20 20 A. I do not. A. 2015 is my recollection. 21 Q. But it's your understanding that there may 21 Q. So maybe around the time of this --22 be one that postdates August 17th, 2015; is that 22 effective date of this document? 23 23 correct? MR. O'CONNOR: Objection to form. 24 24 A. I believe there is. A. I don't know the exact time.

- 1 BY MR. KO:
- Q. Fair enough. Who took over or who was
- 3 Jennifer's predecessor?
- 4 A. I don't know that she had had a
- 5 predecessor, and I don't know that this position --
- 6 that this position exists. So --
- Q. In other words, you don't know if -- prior
- 8 to Jennifer being the SOM data analyst and being on the
- 9 SOM leadership team, that position was not in existence
- 10 at Mallinckrodt? Is that your testimony?
- MR. O'CONNOR: Objection to form.
- 12 A. I'm sorry. Your question is confusing me,
- 13 because you said the predecessor, right, to Jen? I'm
- 14 sorry. Go ahead.
- 15 BY MR. KO:
- Q. Yeah. No, and I can see I was confusing
- because I was initially going to ask who took over for
- 18 Jen, but I also wanted to get an understanding --
- 19 A. Okav.
- Q. -- of who was in place, if anyone, before
- 21 Jen.
- 22 A. Yeah.
- Q. So I apologize. So the record is clear,
- 24 was there a senior data analyst for the SOM program

- Q. Got it. And who is that individual that
- ² plays the role of the new position that you don't
- 3 recall the title of?
 - A. Yes. It's a -- I believe I identified her
- ⁵ earlier today, but I only recall her first name.
- 6 Rochelle
- Q. I see. And generally speaking, what are
- 8 her responsibilities?
- 9 A. One of her responsibilities is going to be
- 10 reviewing any chargeback data that we may have on
- 11 pharmacies of concern, doing some record reviews, and
- 12 there's other things in her job description, but I
- don't recall them all, so -- but she is part of the SOM
- 14 team.
- Q. With respect to the chargebacks, what is
- 16 your understanding of what the chargeback data
- consisted of or consists of today?
- MR. O'CONNOR: Objection to form and
- 19 scope.
- A. It would be pharmacy, name, distributor
- 21 that distributes to the pharmacy, and what Mallinckrodt
- 22 product is involved in the chargeback.
- 23 BY MR. KO:
- Q. Is it accurate to also say that the

Page 219

- 1 prior to Jennifer?
- A. So -- I don't believe so, but Jen's time
- ³ goes back to 2011.
- 4 Q. And what were Jennifer's roles and
- ⁵ responsibilities as a senior data analyst for the SOM
- 6 team?
- A. She reviewed the peculiar, unusual reports
- 8 that were produced twice a day. She was one of the
- 9 analysts that reviewed those.
- Q. And the purpose of her review was to
- 11 determine whether or not the peculiar or unusual order
- 12 would be suspicious sufficient to notify the DEA;
- 13 correct?
- 14 A. Correct.
- O. And after Jennifer left in the 2015 time
- period, who took over for her as a senior data analyst?
- A. I think that position went away and a new
- 18 position was created.
- Q. I see. And what was that new position?
- A. I don't recall what the new position is.
- Q. Does that new position currently exist as
- 22 part of the SOM leadership team that you're a part of?
- A. Part of the SOM team. I don't believe
- 24 part of the leadership team.

1 chargeback data reveals a -- the pharmacy or clinic

Page 221

- 2 that purchases the Mallinckrodt controlled substance or
- 3 Mallinckrodt pharmaceutical from a distributor?
- 4 MR. O'CONNOR: Objection to form.
- 5 A. Yes.
- 6 BY MR. KO:
- 7 Q. And Mallinckrodt is currently utilizing
- 8 that chargeback data in connection with its SOM
- 9 program; correct?
- 10 A. Correct.
 - Q. And Mallinckrodt has in the past utilized
- 12 the chargeback data in connection with its SOM program;
- 13 correct?
- 14 A. Correct.
- 15 Q. And I believe Mallinckrodt began utilizing
- 16 this information as early as 2010. Is that accurate to
- 17 state?
- 18 A. Yes.
- 19 Q. And Mallinckrodt has been paying
- 20 distributors chargeback amounts pursuant to agreements
- 21 it has with the distributors for as long as -- well,
- 22 strike that.
- Do you have an understanding of when
- 24 Mallinckrodt first entered into an agreement with a

| Page | 222 |
|------|-----|
| | |

- 2 amounts to its customers?
- 3 MR. O'CONNOR: Objection to scope.
- 4 A. No.
- 5 BY MR. KO:
- 6 Q. Do you have any recollection of whether
- 7 that was before or after 2005?
- 8 MR. O'CONNOR: Same objection.
- 9 A. No.
- 10 BY MR. KO:
- Q. Turning back to this document. Here we
- 12 have -- I know we have talked about the difference
- 13 between two tiers and three tiers.
- 14 A. Uh-huh.
- Q. But here we have a reference to three
- 16 tiers. Do you see that?
- 17 A. Yes.
- Q. And I know -- so earlier you said that you
- 19 believe that beginning in 2012 Mallinckrodt had
- utilized just the two-tier system; correct?
- 21 A. Correct.
- Q. So does this refresh your recollection at
- 23 all that Mallinckrodt actually moved back to a
- 24 three-tier system at some point in time?

- Page 224
- 1 exist in any way in Mallinckrodt's SOM program today?
 - A. I don't believe it does.
- Q. So would it be fair to say that the
- 4 current iteration of Mallinckrodt's SOM program
- 5 contains the first two tiers mentioned in this
- 6 document?

2

10

- A. Yes.
- 8 Q. So at some point in time the third tier
- 9 was removed, but you don't recall when?
 - A. Correct.
- 11 Q. All right. You can set that one aside.
- 12 So your counsel just received his wish, and probably
- 13 yours too. That was the last policy that we're going
- 14 to go over today.
- A. I can feel the air-conditioning kicking on
- 16 already.
- Q. I'm going to hand you a copy of what has
- been marked as Gillies Exhibit 25.
- 19 [Exhibit Mallinckrodt-Gillies-025
- 20 marked for identification.]
- Q. And I just have a few quick questions
- 22 about this.
- For the record, this is an e-mail dated
- 24 March 10th, 2009, from Wendy "Slab" to Karen Harper,

Page 223

- A. I see it there. My recollection was we
- ² were -- had two tiers, but there is a third tier listed
- 3 here.
- Q. And currently as it stands now, however,
- 5 there is just a two-tier system; correct?
- 6 A. That's my understanding.
- 7 Q. And when did -- how long has
- 8 Mallinckrodt's two-tier system been in effect?
- 9 A. I'm sorry. I don't know. I thought it
- 10 was from September of 2012, so clearly there was a
- change, according to this document.
- Q. Sure. And so it's fair to say that as of
- 13 August 17th, 2015, Mallinckrodt is utilizing a
- 14 three-tier structure to determine whether or not an
- 15 order is suspicious?
- A. That's what it says at this time.
- Q. And with respect to the third tier,
- 18 there's a reference made to a monthly limit placed on a
- 19 customer based on customer bill-to address for a
- 20 particular SKU for a particular amount.
- 21 Did I read that correctly?
- 22 A. Yes.
- Q. And as far as you understand the current
- 24 iteration of Mallinckrodt's SOM program, does that tier

- Page 225
 1 ending in Bates 263874, and containing an attachment
- 2 that begins at 875.
- Do you know who Wendy "Slab" is?
- 4 A. I don't recall who she is. And I do
- ⁵ believe you pronounce it Wendy Slaby.
- 6 Q. Wendy Slaby. Thank you.
- 7 A. Uh-huh.
- 8 Q. This appears to be a flowchart of how a
- 9 peculiar order -- or excuse me.
- This appears to be a flowchart of how a
- 11 suspicious order is identified after it is identified
- 12 as a peculiar order. Is that fair to say?
- A. I'm sorry. Could you say that one more
- 14 time?
- Q. Yeah. It was a bad question. Let me ask
- 16 again.

- Earlier we had discussed the concept of a
- 18 multitiered structure for which Mallinckrodt first
- 19 identified a particular order and then did continued
- analysis to determine whether or not it was suspicious
- 21 sufficient to notify the DEA; correct?
- 22 A. Correct.
 - Q. And this document appears to be a
- 24 flowchart reflecting that process. Is that fair to

| | | _ | |
|--|--|--|--|
| | Page 226 | | Page 228 |
| | say? | | reference made to the filing of a peculiar order report |
| 2 | A. Yes. | | with annotation. Do you see that? |
| 3 | Q. And you don't need to count all the boxes, | 3 | A. Yes. |
| 4 | but there appear to be several boxes of analyses that | 4 | Q. And I believe that peculiar order |
| 5 | Mallinckrodt is undergoing to determine whether or not | 5 | report the intention was to file that report and |
| 6 | the order should ship or whether or not the order | 6 | document the reasons for why a CSR manager believed the |
| 7 | should be notified to the DEA. Is that fair to say? | 7 | report was suspicious or not. Is that accurate? |
| 8 | A. Yes. | 8 | MR. O'CONNOR: Object to form. |
| 9 | Q. And the date of this e-mail attaching this | 9 | A. No, I think the way you phrased the |
| 10 | flowchart is from March of 2009; correct? | 10 | question, my answer would be no. |
| 11 | A. Correct. | 11 | BY MR. KO: |
| 12 | Q. So at least as of the date of this e-mail, | 12 | Q. Okay. Do you recall ever seeing any |
| 13 | this appears to be a flowchart that Mallinckrodt is | 13 | peculiar order reports with annotations from customer |
| 14 | trying to follow to determine whether or not an order | 14 | service rep managers in the 2008 or 2012 time period? |
| 15 | is suspicious after it is identified as peculiar; | 15 | A. No. |
| 16 | correct? | 16 | Q. Have you seen any peculiar order reports |
| 17 | A. Yes. | 17 | |
| 18 | Q. And just so I understand clearly, is it | 18 | manager ever in connection with Mallinckrodt's SOM |
| 19 | accurate to state that this analysis only occurs after | 19 | policy? |
| 20 | an order is identified as peculiar? | 20 | A. I don't recall seeing any. |
| 21 | A. Yes. | 21 | Q. You can actually set that document aside. |
| 22 | Q. So none of these factors are examined if | 22 | |
| 23 | the peculiar order algorithm we've discussed before is | 23 | Now, earlier today we had discussed |
| | not triggered; correct? | | Mallinckrodt's retention of Frank Sapienza and Howard |
| 24 | not triggered, correct: | 21 | Wallinekrout's retention of Frank Sapienza and Howard |
| | | | |
| | Page 227 | | Page 229 |
| 1 | Page 227 A. Correct. | 1 | Page 229 Davis in connection with its CSA obligations in general |
| 1 2 | _ | 1 2 | Davis in connection with its CSA obligations in general |
| | A. Correct. | | Davis in connection with its CSA obligations in general |
| 2 3 | A. Correct.Q. And with respect to some of these | 2 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or |
| 2 3 | A. Correct.Q. And with respect to some of theseanalyses for example, the annotate report with | 2 3 4 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or |
| 3 4 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? | 2 3 4 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in |
| 2 3 4 5 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. | 2 3 4 5 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? |
| 2 3 4 5 6 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews | 2 3 4 5 6 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. |
| 2 3 4 5 6 7 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be | 2 3 4 5 6 7 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? |
| 2 3 4 5 6 7 8 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. | 2 3 4 5 6 7 8 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. |
| 2 3 4 5 6 7 8 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether | 2 3 4 5 6 7 8 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and |
| 2 3 4 5 6 7 8 9 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? | 2 3 4 5 6 7 8 9 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any |
| 2 3 4 5 6 7 8 9 10 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? A. I have no recollection of that. | 2 3 4 5 6 7 8 9 10 11 12 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any other individuals or entities that Mallinckrodt |
| 2 3 4 5 6 7 8 9 10 11 12 13 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? A. I have no recollection of that. Q. Do you recall ever seeing any annotated | 2 3 4 5 6 7 8 9 10 11 12 13 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any other individuals or entities that Mallinckrodt retained in connections with its duties to design and |
| 2 3 4 5 6 7 8 9 10 11 12 13 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? A. I have no recollection of that. Q. Do you recall ever seeing any annotated reports from CSR managers during the 2008 to 2012 time | 2 3 4 4 5 6 6 7 8 8 9 10 11 12 13 14 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any other individuals or entities that Mallinckrodt retained in connections with its duties to design and implement a suspicious order monitoring program? |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? A. I have no recollection of that. Q. Do you recall ever seeing any annotated reports from CSR managers during the 2008 to 2012 time period? | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any other individuals or entities that Mallinckrodt retained in connections with its duties to design and implement a suspicious order monitoring program? A. Time frame? |
| 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | A. Correct. Q. And with respect to some of these analyses for example, the annotate report with explanation do you see that? A. Yes. Q. And apparently that was supposed to be done by the customer service rep manager who reviews the peculiar order report. Do you see that? A. Yes. Q. Do you have any understanding of whether or not this annotated report was documented in any way? A. I have no recollection of that. Q. Do you recall ever seeing any annotated reports from CSR managers during the 2008 to 2012 time period? A. I do not recall that. | 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | Davis in connection with its CSA obligations in general and its SOM obligations in particular. Were there any other individuals or entities that Mallinckrodt retained to assist in implementing its SOM program? A. Yes. Q. And who are these individuals or which entities would these be? A. I'll give you the entity, Buzzeo. Q. And so in addition to Frank Sapienza and Howard Davis and the entity Buzzeo, were there any other individuals or entities that Mallinckrodt retained in connections with its duties to design and implement a suspicious order monitoring program? A. Time frame? Q. At any time. |
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| Page | 230 |
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- Q. And approximately what time period was that from?
- A. My recollection was the 2016 time frame.
- 4 Q. So fairly recently?
- 5 A. Yes.
- 6 Q. And do you have any -- I know you don't
- ⁷ recall the name of the entity, but do you recall what
- 8 they were retained to do?
- 9 A. I do not, but it was another former DEA
- ¹⁰ official.
- Q. I see. So it was an individual that was
- 12 retained?
- A. No, it was a company.
- 14 Q. I see.
- A. Yeah. But the individual that the company
- ¹⁶ dealt with was a former DEA official.
- Q. Got it. And do you have any recollection
- 18 of what they were -- general recollection --
- 19 A. I do not.
- Q. -- of what they were retained to do?
- 21 A. No.
- Q. Going back to Buzzeo. When were they
- ²³ retained, and for approximately how long?
- MR. O'CONNOR: I'm going to object to --

- 1 advise Mallinckrodt regarding its SOM obligations?
 - A. Yes.
 - Q. Well, let me ask again, because I don't
 - 4 think that was a yes-or-no question. But was -- for
 - 5 what general purpose did Mallinckrodt retain Buzzeo
 - 6 for?
 - A. To assist us in our SOM efforts.
 - 8 Q. And was there any particular aspect of the
 - 9 SOM efforts that Buzzeo advised Mallinckrodt on?
- 10 A. Yes.
- Q. And what were those aspects?
- 12 A. Do I have a privilege?
- MR. O'CONNOR: I mean, we can go off the
- 14 record.
- MR. KO: Sure. Let's do it. Sure.
- MR. O'CONNOR: Yeah.
- MR. KO: We'll go off the record for a
- 18 moment.
- THE VIDEOGRAPHER: We are going off the
- 20 record at 3:30 PM.
- [A brief recess was taken.]
- THE VIDEOGRAPHER: We are back on the
- 23 record at 3:38 PM.
- 24 BY MR. KO:

- 1 Buzzeo was retained in connection with this litigation
- ² in 2018 in connection with suspicious order monitoring,
- 3 and so John, I'm going to instruct you not to answer
- 4 with respect to anything beyond the fact of the
- 5 engagement.
- 6 BY MR. KO:
- 7 Q. Okay. So can I --
- 8 A. Okay.
- 9 Q. Can I accept that representation then made
- 10 by your counsel? Is it accurate to say that
- 11 Mallinckrodt retained Buzzeo in connection with this
- 12 litigation in 2018?
- 13 A. Okay. Yes.
- Q. Apart from the retention of Buzzeo for
- 15 purposes of this litigation in 2018, was Buzzeo
- 16 retained at any time prior to that by Mallinckrodt in
- 17 connection with its SOM responsibilities?
- 18 A. Yes.
- Q. And when was that?
- A. My recollection is that we utilized them
- 21 as early as 2012.
- Q. And for what purpose?
- A. For SOM purposes.
- Q. Any specific purpose, or just generally to

Q. So the question that I had asked prior to

Page 233

- ² taking that short break was whether or not there was a
- ³ particular aspect of the SOM efforts that Buzzeo
- 4 advised Mallinckrodt on, and I believe you said the
- 5 answer was yes, and then I had asked you what aspects,
- 6 and so I'll repeat that question now.
- What aspects was Buzzeo retained to advise
- 8 Mallinckrodt on regarding Mallinckrodt's SOM efforts?
- 9 MR. O'CONNOR: And I'm going to object on
- 10 scope and attorney-client privilege with respect to the
- 11 2018 engagement through outside counsel, but you can
- 12 answer with respect to other engagements.
- A. So on the other engagements -- those were
- 14 not SOM engagements.
- 15 BY MR. KO:
- Q. So to be clear, in 2012, when you were
- ⁷ saying earlier that Mallinckrodt had retained Buzzeo,
- 18 that was not in connection with any SOM efforts?
- 19 A. That's correct. I misspoke if that's what
- I had said.Q. And in 2012 then what -- for what purpose
- 22 was Buzzeo retained by Mallinckrodt for?
- MR. O'CONNOR: Object to scope, but you
- 24 can answer.

- 1 A. There were recordkeeping discussions that
- 2 they were providing us advice on and reviewing
- ³ security.
- 4 BY MR. KO:
- ⁵ Q. Recordkeeping discussions regarding what
- 6 records?
- A. Records that we needed to maintain,
- 8 biannual inventories, records that the DEA may ask for
- ⁹ if they come and do an inspection.
- Q. I see. And by security, what do you mean?
- 11 A. The security practices at our Hobart
- 12 facility.
- Q. Understood. And how long was their
- 14 retention during that 2012 time period?
- MR. O'CONNOR: Object to scope.
- A. My recollection is several months.
- 17 BY MR. KO:
- Q. So other than -- so now that I
- 19 understand -- and thank you for the clarification
- 20 regarding their role in 2012.
- So other than Frank Sapienza and Howard
- 22 Davis and potentially this other entity that you don't
- ²³ recall, were there any other individuals or entities
- 24 that Mallinckrodt retained for purposes of assisting

Page 236

Page 237

- 1 managers, Mallinckrodt also employs customer service
- ² representatives; correct?
- A. Correct.
- MR. O'CONNOR: Same objections.
- 5 BY MR. KO:
- 6 Q. And generally speaking, what's your
- understanding of what customer service
- 8 representatives -- what function they perform?
- 9 MR. O'CONNOR: Object to scope.
 - A. So the customer service reps review every
- 11 order that comes in and make sure that all the
- 12 information is there, and --
- 13 BY MR. KO:

10

- Q. And when you say every order, I just want
- 15 to make sure I understand what you're saying when you
- 16 mean every order. Is this every order ever between
- 17 Mallinckrodt and any customer, or are you talking about
- 18 every peculiar order or unusual order? What do you
- 19 mean by every order?
- 20 A. So --
- 21 MR. O'CONNOR: Object to form.
- A. So the customer service reps review every
- 23 order. I might not have been clear earlier. Customer
- 24 service reps review every order. The customer service

Page 235

- ¹ Mallinckrodt with its SOM obligations?
- A. No, not that I can recall.
- ³ Q. Okay. Thank you. Now, you're familiar
- 4 with -- well, you are familiar with the compensation
- ⁵ structure of certain customer service reps and national
- 6 account managers at Mallinckrodt; correct?
- 7 MR. O'CONNOR: Object to form and scope.
- 8 A. I don't recall their compensation
- ⁹ packages.
- 10 BY MR. KO:
- Q. Are you familiar with the term NAMs or
- 12 national account managers?
- 13 A. Yes.
- Q. Mallinckrodt employs certain national
- 15 account managers; correct?
- 16 A. Correct.
- Q. And they have responsibility with respect
- 18 to Mallinckrodt customers, including wholesale
- 19 distributors; correct?
- MR. O'CONNOR: Objection to scope and
- 21 form.
- 22 A. Yes.
- 23 BY MR. KO:
- Q. And in addition to national account

- 1 managers review those peculiar orders.
- 2 BY MR. KO:
- 3 Q. I see. And --
- 4 A. So I apologize if I misspoke earlier
- 5 today. I might have used those terms synonymously when
- 6 you were asking me a certain question. But the reps
- 7 review every order and the managers review the peculiar
- 8 orders.
- 9 Q. Okay. Thank you for that clarification.
- 10 And by every order, just so I understand clearly, you
- 11 are referring to every order between Mallinckrodt and
- 12 one of its customers, the wholesale distributor;
- 13 correct?
- 14 A. That's correct.
- Q. And with respect to national account
- 16 managers, their compensation is tied to the amount of
- 17 Mallinckrodt prescription opioids they sell to
- 18 customers; is that accurate?
- MR. O'CONNOR: Objection to scope and
- 20 form.
- 21 A. I'm sorry. I don't know that.
- 22 BY MR. KO:
- Q. You have no understanding of how national
- 24 account managers are compensated?

Page 238 1 A. No, I do not. Q. In addition to Heather White, do you 2 MR. O'CONNOR: Same --2 recall anyone else at DEA you discussed DEA's 3 BY MR. KO: 3 investigation with? Q. Do you have any understanding of how A. I believe Susan Baker was part of that customer service representatives are compensated? team. MR. O'CONNOR: Same objection. 6 6 Was she also in the DEA Albany office? 7 A. I do not. She was out of the DEA New York office. 8 MR. KO: And I'll just note for the record Other than Ms. Baker or Ms. White, do you 9 to preserve it that I believe Mr. Gillies was supposed recall discussing DEA's investigation of Mallinckrodt 10 to be prepared to testify regarding any compensation to 10 that led to the memorandum of understanding with any 11 any person or committee with any responsibility for any other DEA individual? 12 of the level of sales of controlled substances or A. No, and this -- sorry. Maybe I 13 opioid products, and so I believe we were expecting 13 misunderstood your question. This would have been pre 14 testimony related to your understanding of that topic, any negotiations on that agreement. So there were and I'll note for the record that it appears that Mr. discussions about the investigation, but pre the 16 Gillies is unprepared to testify on that topic. negotiations, just to make it clear. 17 17 BY MR. KO: Q. I understand. 18 Q. In addition to national account managers 18 A. Okay? 19 Q. Okay. So the record is clear then, and 19 and customer service representatives, do you know any 20 other categories of employees at Mallinckrodt who were the way I understand your testimony, is that you spoke involved in the marketing and sales of Mallinckrodt's with Ms. White and Ms. Baker regarding the DEA's prescription opioids? investigation of Mallinckrodt at some point after 2011 23 A. I do not. 23 but before --24 24 Q. Now, earlier today we had talked about the A. So --Page 239 Page 241 1 memorandum of understanding entered into between Q. -- Mallinckrodt and DEA negotiated the 2 Mallinckrodt and the DEA in 2017. Do you recall that? 2 memorandum of understanding? Is that accurate? 3 A. Yes. A. To be more clear, at some time after June 4 of 2012. 4 Q. Were you involved at all in the 5 negotiations leading up to that memorandum of Q. Okay. And when did the negotiations that 6 led up to the memorandum of understanding begin between 6 understanding? 7 Mallinckrodt and DEA? A. No. Q. Do you have any understanding of when A. My recollection is that they were ongoing Mallinckrodt first became aware that it was being for I think more than a year. 10 formally investigated by the DEA? 10 Q. So at some -- safe to say that the 11 negotiations regarding the memorandum of understanding 11 A. September of 2011. 12 Q. And was that pursuant to a subpoena that began at some time in 2016? 13 13 Mallinckrodt received? A. I believe that's accurate. 14 A. I don't know that. 14 Q. And so your discussions with Ms. White and 15 Q. And a moment ago you said you weren't Ms. Baker regarding DEA's investigation occurred at some point between June of 2012 and before 2016? 16 involved at all in the negotiations leading up to the memorandum of understanding. But were you -- did you 17 A. Correct. have any discussions with DEA regarding their 18 Q. And in connection with the investigation, investigation that led to that memorandum of 19 do you know whether -- well, strike that. 20 understanding? In your discussions with Ms. White and Ms. 21 Baker, were you ever formally interviewed or did you A. Yes. 22 And who did you have those discussions ever sit for any kind of formal interview with the DEA? 23 with? 23

24

Heather White, DEA Albany.

24

Q. Are you aware of whether or not

| Page | 242 |
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- 1 Mallinckrodt had any interviews with any Mallinckrodt
- 2 employee arising out of its investigation of
- 3 Mallinckrodt?
- A. So I'm sorry. Could you repeat that
- 5 question?
- 6 Q. Sure. Are you aware of whether
- 7 Mallinckrodt sat for any interviews -- or strike that.
- 8 Are you aware of whether or not the DEA
- 9 had any interviews with any Mallinckrodt employee
- arising out of the DEA's investigation of Mallinckrodt?
- 11 A. No.
- Q. And do you have knowledge of whether or
- 13 not that is in fact the case, or are you saying you
- 14 don't recall whether or not that occurred?
- A. I have no recollection that anybody was
- 16 interviewed.
- Q. Do you know if any Mallinckrodt employee
- 18 provided any statements -- sworn statements to the DEA
- 19 regarding Mallinckrodt's investigation?
- 20 A. No.
- Q. Or excuse me. Regarding the DEA's
- 22 investigation of Mallinckrodt?
- 23 A. No.
- Q. And do you know -- so in addition to your

1 A. The meeting with the DEA where Susan Baker

Page 244

Page 245

- 2 and Heather White were present discussing their
- 3 investigation.
- Q. I see. And you were present at that
- 5 meeting as well?
- 6 A. I was.
 - O. So in addition to Mr. Weustner, Mr.
- 8 Lohman, and yourself, were there any other Mallinckrodt
- 9 employees that were present at the meeting?
 - A. Not that I can recall.
- Q. And from the DEA's side, other than Ms.
- 12 Baker and Ms. White, were there any other DEA officials
- 13 there?

10

- 14 A. There were.
- Q. And who were they?
- A. One was their special agent in charge of
- 17 their New York office. And I'm sorry, I do not recall
- 18 his name. I believe there was a DEA representative
- 19 from Washington D.C. I'm sorry, I do not remember his
- 20 name. And I can't recall if there was any other DEA
- 21 personnel there.
- Q. And when did this meeting take place?
- A. I don't recall. I'm going to say spring
- 24 2014.

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Page 243

- 1 communications with Ms. White and Ms. Baker, do you
- 2 know whether or not any other Mallinckrodt employees
- 3 communicated with DEA regarding its investigation of
- 4 Mallinckrodt?
- 5 A. Yes.
- 6 O. And which individuals would those be?
- A. Joe Weustner and I believe Don Lohman.
- 8 Q. And you said Joe --
- 9 A. Weustner.
- 10 Q. Joe Weustner?
- 11 A. W-E-U-S-T-N-E-R.
- Q. And what is his job title at Mallinckrodt?
- A. He was a VP associate general counsel.
- Q. In addition to Joe and Don, do you recall
- 15 any other individuals who communicated with the DEA
- 16 regarding their investigation?
- 17 A. No.
- Q. Do you recall whether or not Ms. Harper
- 19 communicated with the DEA regarding their investigation
- 20 of Mallinckrodt?
- A. I can't recall whether she was at the
- 22 meeting.
- Q. And you just referenced a meeting. What
- 24 meeting are you describing?

- Q. Okay. Thank you. That's helpful.
- ² Following the -- this meeting, do you recall any other
- 3 meetings in which you were present with the DEA
- 4 regarding its investigation of Mallinckrodt?
- 5 A. No.
- 6 Q. And in addition to this meeting, do you
- 7 recall any other meetings, regardless of whether or not
- 8 you were involved with the DEA, regarding its
- 9 investigation of Mallinckrodt?
- 10 A. I do not.
- Q. You don't recall, or you don't believe any
- 12 such meetings took place?
- 13 A. I don't recall.
 - Q. Now, the agreement resulted among other
- 15 things in a \$35 million payment made by Mallinckrodt to
- 16 the Department of Justice; correct?
- 17 A. Yes.
- Q. Were you involved -- or who was involved
- 19 in the negotiation of the monetary fine?
- MR. O'CONNOR: Objection to form.
- 21 A. There was legal counsel involved.
- 22 BY MR. KO:
- Q. So is it your understanding that it was
- 24 primarily handled by Mr. Lohman and Mr. Weustner?

Page 246 1 A. Yes. 1 investigations performed by any entity regarding 2 Q. Was there anyone outside of the legal ² Mallinckrodt's manufacturing or distribution of its 3 department or legal counsel that handled the opioid products? 4 negotiations over the monetary fine that Mallinckrodt MR. O'CONNOR: Objection to form. 5 paid to the DEA? A. I don't know of any. MR. O'CONNOR: Objection to form. BY MR. KO: 7 A. Within Mallinckrodt? Q. Were you -- was it the case that earlier 8 BY MR. KO: 8 last year in the beginning of 2018, prosecutors from the Southern District of Florida had issued grand jury 9 Q. Yes. 10 A. No. subpoenas to Mallinckrodt regarding its manufacturing Q. So you don't believe anyone outside of and distribution of prescription opioids? 11 legal counsel handled --12 12 A. I'm not aware of that. 13 A. I don't recall anyone else outside legal 13 Q. You're not aware of that? Are you aware 14 counsel. of any other subpoenas issued by the Department of -- being involved in the discussions 15 Justice at any time regarding Mallinckrodt's marketing 16 about the monetary fine imposed on Mallinckrodt; or manufacturing of any of its generic or branded 17 correct? opioid products? 18 A. Correct. 18 A. I am not. 19 Q. Now, in addition to DEA's investigation 19 Q. So are you aware of any 2017 subpoena by which resulted in the 2017 memorandum of understanding the Department of Justice regarding Mallinckrodt's and the \$35 million fine, there have been other manufacturing and marketing of Exalgo, Xartemis, and 22 investigations by other government entities into Roxicodone, among other products? Mallinckrodt; is that fair to say? 23 A. I am not. 24 MR. O'CONNOR: Objection to form. 24 Are you aware of any civil investigative Page 247 Page 249 A. What government entities? 1 demands from any other officials -- from any officials 2 BY MR. KO: ² in any state in the United States regarding 3 Q. Sure. Fair enough. Are you aware of any 3 Mallinckrodt's marketing and distribution of 4 other investigations done by any senators with respect prescription opioids? 5 to Mallinckrodt's marketing or distribution of its A. State authorities? I'm not aware of any. opioid products? 6 Q. Are you aware of any civil investigative 7 MR. O'CONNOR: Object to form. demand by the State of Washington regarding 8 A. I'm aware of a senator requesting 8 Mallinckrodt manufacture and distribution of its information. prescription opioids? 10 BY MR. KO: 10 A. I am not. 11 Q. And which senator was that? 11 Q. Are you aware of Missouri's civil Claire McCaskill. investigative demand of information related to 13 Mallinckrodt's manufacture and distribution of its Q. And when was that? 14 A. I don't recall what the time frame was. prescription opioids? 15 Q. And who was involved in preparing the 15 A. I am not. information in response to Senator McCaskill's request? 16 Q. Now, one of the -- as we discussed earlier 16 17 A. My understanding, legal counsel. today, one of the primary responsibilities of the DEA 18 Q. And do you have any understanding of what compliance group is to communicate with the DEA 19 information Senator McCaskill requested of regarding Mallinckrodt's annual quota request. Is that Mallinckrodt? 20 accurate? 21 A. I do not. 21 A. Yes. 22 Q. In addition to Senator McCaskill's request 22 Q. And there are different types of quotas 23 and the DEA's investigation which resulted in the 2017 set by the DEA; correct? memorandum of understanding, are you aware of any other 24 A. Correct.

Page 250 Page 252 1 Q. And can you describe to the court what 1 process? 2 2 those different types of quotas consist of? A. I am not. Who on the DEA compliance team is A. For the individual controlled substance 4 responsible for working with the DEA and Mallinckrodt's 4 products, the DEA has a set quota that they then give 5 to the manufacturers. annual quota request today? And is that a reference to a manufacturing A. Karen Harper. 7 quota? Q. And in addition to Karen Harper, are there 8 8 any other individuals that assist her in the annual Yes. A. Q. And in addition to the manufacturing quota request? 10 quota, there's also -- the DEA has -- provides guidance 10 A. It's my recollection that Dave Hunter 11 on procurement quota as well; correct? 11 assists her on the manufacturing for the St. Louis 12 A. Correct. plant, and Eileen Spaulding, it's my understanding, 13 Q. And what does procurement quota consist assists her on the procurement. 14 of? 14 Q. And is it your understanding that Ms. A. So the manufacturing quota would be for Harper had the primary responsibility of working with 15 16 our St. Louis facility, and the procurement quota would the DEA regarding Mallinckrodt's annual quota be for our Hobart facility on the number of tablets request -- or strike that. that we're going to make. How long has Ms. Harper had the 19 responsibility of working with the DEA regarding 19 Q. So in other words, would it be fair to say Mallinckrodt's quota requests? 20 that the procurement quota governs the amount that Mallinckrodt can turn into an actual extended unit 21 A. I know that it predates 2008. 22 22 release or pill -- strike that. Let me ask it a Q. And throughout that time period, there was 23 no other individual who had that primary responsibility different way. 24 The manufacturing quota established by the 24 at Mallinckrodt; is that accurate? Page 251 Page 253 1 DEA governs how much raw product Mallinckrodt can A. Yes. 2 manufacture; correct? Now, we've made mention to -- we've made 3 A. Correct. ³ mention to Mallinckrodt's St. Louis and Hobart 4 Q. And the procurement quota governs how much 4 facilities. Is the St. Louis facility synonymous or 5 of that raw product Mallinckrodt can turn into a pill; different from the Webster Groves facility? 6 correct? A. It's different. 7 Q. And what did the -- can you describe to A. Yes, and in our request to the DEA, we 8 tell them how many pills it's estimated that we would 8 the court what the Webster Groves facility was in 9 make. charge of or what happened at the Webster Groves 10 Q. And so in connection with your 10 facility? 11 communications with the DEA, are you saying that there 11 MR. O'CONNOR: Objection to form. 12 is a separate procedure with respect to the procurement 12 A. Our Webster Groves facility is an R & D 13 facility. 13 quota relative to the manufacturing quota, or would you 14 regularly communicate with the DEA regarding both BY MR. KO: 15 quotas? 15 Q. Got it. Was there any manufacturing of 16 opioids done at the Webster Groves facility? A. Yeah. 16 17 17 MR. O'CONNOR: Objection to form. A. Time frame? 18 A. Both quotas. 18 Q. At any time. 19 BY MR. KO: 19 Yes. A. 20 Q. And regarding the manufacturing quota set 20 O. And when was that? 21 by the DEA, they generally set that once a year; 21 A. November 2018.

22

23

24

Q.

Uh-huh.

And are you currently involved in that

A. That's my understanding.

22 correct?

23

24

Prior to November of 2018, was there any

So somewhat recently?

| se | Ή | :17-md-02804-DAP_Doc#: 3013-11 Filed ighly confidential - Subject to | : 1 : 1 | 2/18/19r66.8f.85.deagelD1#:446057iew |
|-------|--|--|--|--|
| | | Page 254 | | Page 256 |
| | 1 | manufacturing that occurred at the Webster Groves | 1 | A. And then let me answer that. Okay. So |
| | 2 | facility? | 2 | could you repeat your question now? |
| | 3 | A. I'm unaware of any manufacturing taking | 3 | Q. Sure. Do you have any recollection of |
| | 4 | place. | 4 | whether or not the quota whether or not the SOM |
| | 5 | Q. And prior to 2018, the Webster Groves | 5 | program that Mallinckrodt implemented was tied in any |
| | 6 | facility was primarily utilized as an R & D facility; | 6 | way to Mallinckrodt's quota requests? |
| | | is that accurate? | 7 | MR. O'CONNOR: Object to form. |
| | 8 | A. Was and is. Yeah. | 8 | A. No. |
| | 9 | Q. I'm going to hand you a copy of what's | 9 | BY MR. KO: |
| 1 | 10 | been marked as Gillies Exhibit 26. | 10 | Q. Did Mallinckrodt ever learn from the DEA |
| 1 | 11 | [Exhibit Mallinckrodt-Gillies-026 | 11 | if that if it had a robust SOM program it would more |
| 1 | 12 | marked for identification.] | | likely be able to maximize its quota requests? |
| 1 | 13 | Q. And for the record, this ends in Bates | 13 | A. No. |
| | 14 | 3044340, and it's an e-mail chain from June 20th, 2012, | 14 | Q. Did you ever did you review any |
| | 15 | between Kenneth Yamashita and Eileen Spaulding. | | documents in preparation for this deposition today that |
| | 16 | And I just have a quick question on this | 16 | had any connection between quota requests and |
| | 17 | e-mail. Feel free to review it if you need to in | 17 | Mallinckrodt's SOM program? |
| | | responding to my question. | 18 | A. Not that I recall. |
| | 19 | A. Uh-huh. | 19 | |
| | 20 | | | Q. You can set that one aside. So earlier we |
| | | Q. But at the top, Ken indicates, quote, did | 20 | had talked about the meeting that Mallinckrodt had with |
| | | you get the impression now that if our quota | 21 | DEA in August of 2011. Do you recall that? |
| | | justification and suspicious order monitoring program | 22 | A. Yes. |
| 2 | 23 | is good, we will get the quota or at least some | 23 | Q. And do you recall who requested that |
| | | | | |
| | | portion, end quote. | | meeting? |
| | | portion, end quote. Page 255 | | meeting? Page 257 |
| | | portion, end quote. Page 255 Did I read that correctly? | 24 | Page 257 A. I know that we had requested a meeting |
| | 24 | portion, end quote. Page 255 | 24 1 2 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this |
| | 24 | portion, end quote. Page 255 Did I read that correctly? | 24 1 2 | Page 257 A. I know that we had requested a meeting |
| | 1 2 3 | portion, end quote. Page 255 Did I read that correctly? A. Yes. | 1 2 3 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. |
| | 1 2 3 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken | 1 2 3 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request |
| | 1 2 3 4 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? | 1 2 3 4 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. |
| | 1 2 3 4 5 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. | 1 2 3 4 5 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this |
| | 1 2 3 4 5 6 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? | 1 2 3 4 5 6 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were |
| | 1 2 3 4 5 6 7 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. | 1 2 3 4 5 6 7 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to |
| 2 | 1 2 3 4 5 6 7 8 | portion, end quote. Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart | 1 2 3 4 5 6 7 8 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? |
| 2 | 1 2 3 4 5 6 7 8 9 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? | 1 2 3 4 5 6 7 8 9 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. |
| 1 1 1 | 1 2 3 4 5 6 7 8 9 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the | 1 2 3 4 5 6 7 8 9 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to |
| 1 3 3 | 1 2 3 4 5 6 7 8 9 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. | 1 2 3 4 5 6 7 8 9 10 11 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we |
| | 1 2 3 4 5 6 7 8 9 10 11 12 13 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of | 1 2 3 4 5 6 7 8 9 10 11 12 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. |
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| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of whether or not the quota justification or strike that. | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. BY MR. KO: Q. Okay. And was another topic of the |
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| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of whether or not the quota justification or strike that. He's asking whether or not the SO if the SOM program is adequate that Mallinckrodt would | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. BY MR. KO: Q. Okay. And was another topic of the meeting issues with respect to Mallinckrodt's quota requests? |
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| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of whether or not the quota justification or strike that. He's asking whether or not the SO if the SOM program is adequate that Mallinckrodt would obtain the quota that they sought. Do you have any recollection of whether or | 24 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. BY MR. KO: Q. Okay. And was another topic of the meeting issues with respect to Mallinckrodt's quota requests? A. I don't recall that. Q. I'm going to hand you a copy of what's |
| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of whether or not the quota justification or strike that. He's asking whether or not the SO if the SOM program is adequate that Mallinckrodt would obtain the quota that they sought. Do you have any recollection of whether or not the quota justification or the quota request was | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. BY MR. KO: Q. Okay. And was another topic of the meeting issues with respect to Mallinckrodt's quota requests? A. I don't recall that. Q. I'm going to hand you a copy of what's going to be marked as Gillies Exhibit 27. |
| | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | Page 255 Did I read that correctly? A. Yes. Q. First of all, do you know who Ken Yamashita is? A. Yes. Q. And who is he? A. He was the head of our Hobart facility. Q. And what do you and by head of Hobart facility, what exactly do you mean? A. He was he ran the administration of the facility. Q. And he's asking a question to Eileen of whether or not the quota justification or strike that. He's asking whether or not the SO if the SOM program is adequate that Mallinckrodt would obtain the quota that they sought. Do you have any recollection of whether or not the quota justification or the quota request was ever tied to Mallinckrodt's SOM program? | 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 | Page 257 A. I know that we had requested a meeting with the DEA since the spring of 2011, and I think this August meeting was in response to our ongoing request to meet with them. Q. And is it fair to say that during this meeting, two of the issues that were discussed were Mallinckrodt's SOM program and issues with respect to Mallinckrodt's quota requests? MR. O'CONNOR: Objection to form. A. I know one of the issues was we wanted to tell DEA about our SOM program and everything that we were doing. BY MR. KO: Q. Okay. And was another topic of the meeting issues with respect to Mallinckrodt's quota requests? A. I don't recall that. Q. I'm going to hand you a copy of what's going to be marked as Gillies Exhibit 27. [Exhibit Mallinckrodt-Gillies-027 |

23 you?

A. Yes.

23 BY MR. KO:

Q. Sure.

Page 258 Page 260 1 Q. And did you review this document in 1 discussed during this meeting. 2 preparation for this deposition today? A. Uh-huh. 3 A. No. Q. But does this refresh your recollection at Q. And how does this document look familiar 4 all as to what aspects of quota were discussed with the 5 to you? Did you review it at some point separate and DEA during this meeting? apart from preparing for this deposition? A. No. Yes. Q. No reason to dispute that quota issues 8 were discussed with the DEA during August 23rd, 2011, And approximately when do you think that 9 was? though; right? 10 A. I believe this is one of the documents I 10 MR. O'CONNOR: Objection to form. 11 reviewed after I joined Mallinckrodt. A. So it's a bullet point on this slide. I 11 12 don't know whether they actually talked about it. I Q. And as I understand it, I believe this is 13 a deck that Mallinckrodt used during that meeting and have no recollection of that. presented it to the DEA. 14 BY MR. KO: 15 Is that consistent with your 15 Q. Fair enough. You can set that aside. I'm 16 understanding? going to hand you a copy of what's marked as Gillies 17 17 Exhibit 28. A. Yes. 18 Q. And I just have a few quick questions 18 [Exhibit Mallinckrodt-Gillies-028 19 about it. On the second page of this deck there is a 19 marked for identification.] 20 reference made to suspicious order monitoring 20 Q. And for the record, this document is presentation agenda. Do you see that? titled draft notes for SOM steering committee meeting, 22 A. Yes. 9-28-11, and it ends in Bates 2077756. 23 23 Q. So just so the record is clear, the And Mr. Gillies, this appears to be --24 primary topic of the DEA meeting in August of 2011 was 24 well, earlier we had went over certain policies Page 259 Page 261 1 regarding Mallinckrodt's SOM program; correct? 1 regarding Mallinckrodt's SOM, and in some of those 2 2 policies there was reference made to a steering A. Correct. 3 MR. O'CONNOR: Objection to form. committee; correct? 4 BY MR. KO: A. Yes. 5 Q. And if you look at Page 7 of this report, Q. And from time to time members of the 6 there's an additional reference made to subpoenas, SOM steering committee would meet to discuss Mallinckrodt's 7 quota review, and business relationships. Do you see SOM program; correct? 8 that? 8 A. Correct. 9 A. Yes. Q. And this appears to be notes that are 10 Q. And the context of these references is being prepared in connection with the steering 11 being made in the context of the SOM program challenges committee meeting; right? 12 and issues. Do you see that? 12 A. Correct. A. Yes. 13 13 Q. And so halfway down the first page there 14 is a brief recap of the DEA meeting. You see that? 14 Q. So would it be accurate to say that in addition to Mallinckrodt SOM being reviewed at the 15 A. Yes. 16 meeting, Mallinckrodt also discussed challenges and 16 Q. And it appears that their recap is issues with respect to subpoenas it was receiving, SOM being -- that Don is providing the recap, and I imagine quota review, and certain business relationships it that would be Don Lohman? 19 had? 19 A. That would be my understanding. 20 MR. O'CONNOR: Objection to form. 20 Q. And there are a variety of things that are

Q. And do you -- I know a moment ago that you

discussed here, but it appears that the summary of the

meeting, Don indicates that, quote, at our request, on

23 August 23rd, 2011, met with the DEA office of diversion

24 control and quota section in Washington D.C. to discuss

A. That's what this slide says.

21

23

22 BY MR. KO:

| T) | 200 |
|-------|-----|
| Page | 262 |
| 1 450 | |

- 1 our SOM program, which monitors suspicious orders of
- 2 controlled substances and our outstanding quota
- ³ requests, end quote.
- 4 Did I read that correctly?
- 5 A. Yes.
- 6 Q. So is it accurate to say that -- and just
- ⁷ so the record is clear -- that during the August 2011
- 8 meeting, two of the topics that were discussed were
- 9 suspicious order monitoring and outstanding quota
- 10 requests of Mallinckrodt?
- 11 A. Yes.
- Q. That's all I have with that document. I'm
- 13 going to hand you a copy of what's been marked as
- 14 Gillies Exhibit 29.
- 15 [Exhibit Mallinckrodt-Gillies-029
- marked for identification.]
- Q. And for the record, this document ends in
- 18 Bates 284620 and is an e-mail from Karen Harper to
- 19 herself dated Saturday, April 23rd, 2011. And it
- appears to be some notes that she took from a DEA
- 21 conference that she attended.
- 22 Did you -- does this document look
- 23 familiar at all to you?
- 24 A. No.

- Q. Did you review this document in connection
- 2 with your preparing for this deposition today?
- 3 A. No.
- 4 Q. Do you know who Michael Morley is?
- 5 A. I do not.
- 6 Q. Do you know who Kyle Wright is?
- 7 A. I do not.
- 8 Q. Do you have any understanding of how
- 9 frequent members of the DEA compliance team attended
- 10 DEA conferences regarding Mallinckrodt's CSA
- 11 obligations?
- 12 A. I do not.
- Q. Do you know whether or not Mallinckrodt
- 14 employees ever attended DEA conferences regarding their
- 15 CSA obligations?
- 16 A. Yes.
- Q. And do you have any understanding of how
- 18 frequent they attended such conferences?
- A. So can you restate that question? Because
- 20 I may have misunderstood the previous question.
- Q. Well, I had asked you whether or not --
- 22 sure.
- 23 A. Okay.
- Q. I asked you whether or not you were aware

- 1 of whether or not Mallinckrodt employees attended DEA
- ² conferences, and I believe you said yes, and my
- 3 follow-up question was whether or not you had an
- 4 understanding of how frequent they attended such
- 5 conferences.
- 6 A. Okay. So I think I did misunderstand the
- 7 way you phrased it, but that time the answer is yes,
- 8 and I believe it was annually.
- 9 Q. And was it typically the case that Ms.
- 10 Harper would attend?
- 11 A. Yes.
- Q. And do you know any other Mallinckrodt
 - 3 employees that attended any annual DEA conferences?
- A. Eileen Spaulding. Time frame?
- 15 Q. At any time.
 - A. Jen Buist. I can't recall if there was
- 17 anybody else.

16

- Q. At the bottom of this e-mail, Karen Harper
- 19 indicates that, quote, someone in your company is
- 20 accountable for making decisions about customers, SOM.
- 21 All decisions should be documented in file by customer.
- 22 Do you see that?
- 23 A. Yes.
- Q. So is it accurate to say that Karen Harper

Page 265

- 1 is indicating that there should be some sort of
- ² documentation procedure with respect to all decisions
- ³ regarding SOM?
- MR. O'CONNOR: Objection to form.
- 5 A. So can you repeat that question?
- 6 BY MR. KO:
- Q. Sure. Is it accurate to say that Karen
- 8 Harper is indicating that there should be some sort of
- 9 documentation procedure with respect to all decisions
- 10 regarding SOM?
- 11 A. Yes.
- Q. And we had talked about it a little bit
- before, but are you aware of whether or not there was
- 14 any kind of formal documentation procedure regarding
- ¹⁵ Mallinckrodt's SOM in the 2011 time period?
- MR. O'CONNOR: Objection to form.
 - A. I believe there was.
- 18 BY MR. KO:

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- Q. And what is that understanding based upon?
 - A. From reviewing procedures.
- Q. And which -- the same procedures we were
- 22 kind of discussing before?
 - A. Yes.
 - Q. Outside of those procedures, did you

Page 266 1 review any other documents that suggested there was a 1 Q. And we had established that chargeback 2 formal documentation procedure governing the decisions 2 data allowed Mallinckrodt to see where its pills were 3 made by any individuals at Mallinckrodt with respect to going and specifically to which pharmacies and clinics 4 Mallinckrodt drugs were going after Mallinckrodt 4 its SOM? 5 I don't recall that. 5 shipped to its distributors; correct? MR. O'CONNOR: Objection to form. 6 Q. So is it fair to say that at least as of 7 the date of this letter, Mallinckrodt is aware that DEA A. Not all pharmacies. There has to be a 8 is expecting some sort of formal documentation chargeback relationship and corrected as retroactive. MR. O'CONNOR: Counsel, just a heads-up. regarding its SOM decisions and policies? MR. O'CONNOR: Objection to form. 10 By our count, you have about a minute. 11 A. That's what this note references. 11 MR. KO: Okay. I have one more -- I 12 BY MR. KO: 12 thought I had about 15 minutes. But --13 Q. So is it -- I understand that that's what MR. O'CONNOR: You're welcome to check. 14 the note references, but I'm asking you as a 14 How much -designee -- a corporate designee of Mallinckrodt 15 MR. KO: It's your math versus Alison's, 16 sitting here today, yes or no, is it fair to say that 16 but -as of the date of this letter, Mallinckrodt is aware 17 MR. O'CONNOR: How much time -that DEA is expecting some sort of formal documentation 18 MR. KO: Not to put you on the spot, but I procedure regarding its SOM decisions and policies? got one more document. 20 MR. O'CONNOR: Objection to form. 20 MR. O'CONNOR: Okay. THE VIDEOGRAPHER: I've got five hours, 25 21 A. Yes. 21 22 minutes. 22 BY MR. KO: 23 23 Q. And underneath the section Kyle Wright, MR. KO: Okay. 24 there's an indication, quote, I am coming. You don't 24 MR. O'CONNOR: And we had 5:25 for the Page 267 Page 269 1 want me. I can tear you apart. If DEA can see where 1 limit; right? ² drugs are going, Mallinckrodt knows full well where 2 MR. KO: All right. ³ drugs are going. MR. O'CONNOR: But one document quickly. 4 Did I read that correctly? MR. KO: Okay. Thank you for that. 5 A. Yes. 5 BY MR. KO: 6 Q. And so is it fair to say that the DEA Q. There's -- Mr. Gillies, I'm handing you a 7 certainly expects Mallinckrodt to understand where all 7 copy of a document that's been marked as Gillies 8 of its drugs are going even after Mallinckrodt ships 8 Exhibit --9 them to its distributor customers? MS. GAFFNEY: 30. 10 MR. O'CONNOR: Objection to form. 10 BY MR. KO: 11 A. I don't know that that's what it's saying, 11 Q. -- 30. Thank you. 12 because our product goes to the distributors and 12 [Exhibit Mallinckrodt-Gillies-030 13 wholesalers. So I don't see a reference that it says marked for identification.] that this goes further beyond that. 14 Q. And for the record, this is a March 18th, 15 2013, correspondence dated -- or I said the date But in this case, the DEA can see, because already -- ending in Bates 8434954. And I have a very 16 they've got all the information, right, through ARCOS. 17 So they see where it goes, so they can see that we're specific question. 18 sending it to the distributors or wholesalers, but 18 A. Okay. 19 because they get the ARCOS information from others, 19 Q. So again, if you need to read more of the 20 they can see where that goes too. document, please feel free to do so. 21 BY MR. KO: 21 But first of all, this appears to be a 22 Q. And we had discussed earlier the concept 22 communication made by an outside counsel for 23 of chargeback data; correct? 23 Mallinckrodt to an assistant U.S. attorney. Is that

24 accurate?

A. Correct.

Page 270 1 A. Yes. Q. And similarly, the next sentence talks 2 Q. And in Section 1 of the document, there is 2 about percentage of chargeback requests for oxycodone 3 30, and this sentence reads from 2009 through 2012, 3 reference made to a certain percentage of oxy 15s and 4 oxy 30s distributed by certain of Mallinckrodt's 4 approximately 98 percent of the total volume by dosage customers; right? 5 unit of oxycodone 30-milligram products manufactured and distributed by Mallinckrodt fell under the Yes. 7 Q. And those customers are the big three chargeback system. distributors and H.D. Smith; correct? 8 Did I read that correctly? 9 A. Correct. 9 A. Yes. And they distributed oxy 15s and oxy 30s; 10 10 MR. O'CONNOR: Same objection. 11 correct? 11 BY MR. KO: 12 12 A. Correct. Q. So is it accurate to say that the vast 13 Q. And turning to the next page -- this is 13 majority of -- if not nearly 100 percent, of all 14 just the final line of questioning. Do you see the oxycodone 15-milligram and oxycodone 30-milligram section Page 3 -- or sorry -- do you see the section orders resulted in a chargeback request by a 16 Question 3? distributor --17 17 A. Just for my reference in the future, if I MR. O'CONNOR: Objection --18 have to go back, could you put the Bates number on it? BY MR. KO: 19 Because you said this was the only Bates number. You 19 Q. -- in the 2009 through 2012 time period? 20 said ending in this number, but is this a new number 20 MR. O'CONNOR: Objection to form and 21 scope. 22 Q. Right. That's just the next page --22 A. Not all, but vast majority. 23 A. Okay. 23 BY MR. KO: 24 -- of the document. So regardless, we're Q. Right. And I said, just so the record is Page 271 Page 273 1 on Page 2 of this document. 1 clear, is it accurate to say that nearly 100 percent of 2 all oxycodone 15-milligram and oxycodone 30-milligram A. Okay. Thank you. 3 Q. And there's a question asked, quote, what 3 orders resulted in a chargeback request by a 4 percentage of sales of oxycodone products involve 4 distributor? customers that fall under the chargeback system. A. It would be --MR. O'CONNOR: Objection to form and 6 Did I read that correctly? 6 7 A. Yes. scope. 8 Q. And the answer that's provided is from A. It would be more accurate to say 96 9 2009 through 2012, approximately 96 percent of the percent and 98 percent. 10 total volume by dosage units of oxycodone 15-milligram 10 BY MR. KO: 11 products manufactured and distributed by Mallinckrodt 11 Q. Okay. Fair enough. So 96 percent of all 12 fell under the chargeback system. 12 oxy 15 orders of Mallinckrodt-manufactured oxy 15 13 resulted in a chargeback request from the 2009 through 13 Did I read that correctly? 14 A. Yes. 2012 time period; correct? 15 Q. So a moment ago you had said not all 15 MR. O'CONNOR: Objection to form, scope. 16 requests -- not all -- sorry -- not all transactions Asked and answered. 16 resulted in a chargeback request? 17 A. Yes. 18 A. That's correct. 18 BY MR. KO: 19 Q. But at least with respect to oxycodone 15 19 Q. And final question. 98 percent of the 20 milligrams, from 2009 to 2012, 96 percent resulted in a 20 total volume of oxycodone 30-milligram products chargeback request; is that accurate? manufactured by Mallinckrodt resulted in a chargeback 21 22 MR. O'CONNOR: Objection to scope. 22 request made by a distributor in the 2009 through 2012 23 time period; correct? 23 A. Yes. 24 BY MR. KO: 24 MR. O'CONNOR: Objection to form, scope.

Page 274 Page 276 1 Asked and answered. 1 long period of time. 2 A. Correct. A. I know. There were approximately four 3 meetings and a videoconference during that time where MR. KO: Okay. Those are all the questions I have. Thank you for your patience. 4 issues were being discussed and Tennessee came up. 5 A. Thank you. Q. So the meetings and the videoconference, THE VIDEOGRAPHER: We are going off the were they specifically about Tennessee? 6 record at 4:32 PM. A. No. 8 8 Q. Have you had any meetings or conversations [A brief recess was taken.] THE VIDEOGRAPHER: We are back on the with your counsel specifically about Tennessee? 10 record at 4:49 PM. 10 11 11 **EXAMINATION** Q. So your discussions about Tennessee with 12 BY MS. HERZFELD: your counsel, all told, would you say -- specifically 13 Q. Mr. Gillies, my name is Tricia Herzfeld, about Tennessee -- how long? and I'm an attorney representing the plaintiffs in the 14 A. With counsel? Tennessee litigation. Are you familiar with the 15 Yes, sir. 16 Tennessee litigation? 16 Several hours. 17 17 A. Yes. Several hours? 18 Q. And what is it that you know about the 18 Yes. 19 Tennessee litigation? 19 Q. And so you said several hours specifically A. That you have a claim against Mallinckrodt about Tennessee? 20 20 21 and others for the opioid crisis. A. Correct. 22 22 Q. What else do you know about it? Q. Then you said several conversations 23 That's about my recollection. 23 between September 2018 and January 2019 were those 24 Do you know who the plaintiffs are in the other things and Tennessee was brought up, so I guess Page 275 Page 277 1 Tennessee litigation? 1 I'm a little confused. 2 A. I do not recall. A. Okay. So there were four meetings with MS. HERZFELD: And before we get going in 3 counsel and a videoconference, and at some point during 4 the deposition today, we're going to lodge our usual those meetings, some issues on Tennessee came up. 5 objections for failure to comply with the MDL protocol, Q. And so each of those meetings would you 6 which has also been entered and established in Dunaway say was roughly how long? 7 (ph) cases. MS. MIKA: Sorry to interrupt the 8 MR. O'CONNOR: And we're going to respond 8 deposition, but you're muted. 9 with our usual objection to your objections. THE REPORTER: Okay, I just turned you 10 MS. HERZFELD: There we go. Okay. guys back on. 11 BY MS. HERZFELD: 11 BY MS. HERZFELD: 12 Q. And Mr. Gillies, what did you do to 12 Q. I'm sorry. And so how long would you say 13 prepare for the Tennessee portion of your deposition 13 each of those meetings was? 14 today? 14 A. So four of the meetings were approximately 15 A. I met with legal counsel, and my eight hours. The videoconference was four hours. And 16 recollection is that some of the documents that I then combined, several hours over that time frame was reviewed might be associated with that matter. 17 devoted to Tennessee. 18 Q. How long would you say you met with your 18 Q. And who was on those calls? 19 counsel specifically about the Tennessee matter? 19 A. So on the call was Andrew O'Connor and 20 A. Several hours. 20 Bill Davison. 21 Q. And when was that? 21 Q. Anybody else? 22 A. Between September and -- September 2018 22 A. No. 23 and January 2019. 23 And what about in the meetings? 24 Q. And so how was that broken up? That's a 24 A. In the meetings would have been Andrew,

Page 278 Page 280 1 Bill, and Josh. Q. Did you search your e-mails or your 2 Q. Anybody else? ² documents for anything having to do with Tennessee 3 3 prior to attending this deposition today? Q. Have you read the Tennessee complaint? A. No. 5 A. I don't think so. Q. Going to Topic 1. What was done by Q. And do you know if the allegations in the Mallinckrodt to ensure compliance with Tennessee state 7 Tennessee complaint are meaningfully different than the statutes and local laws? allegations in the MDL? MR. O'CONNOR: Objection. 9 9 A. I do not. MS. HERZFELD: What's the objection? MR. O'CONNOR: Form and potentially scope. 10 10 MR. O'CONNOR: Objection to form. 11 BY MS. HERZFELD: 11 Form for now. 12 BY MS. HERZFELD: 12 Q. I'm sorry. You said I do not? 13 A. That's correct. Q. Okay. I'm looking here. I just want 14 Q. And I'm sorry. I might have asked you to -- I want to be very clear. So looking at that very this question before. Did you review any first topic, Topic 1 is your procedures, organization, 16 Tennessee-specific documents in preparation for your and personnel assignments, oversight, due diligence, testimony today? and quality control regarding compliance with the CSA 17 18 A. I believe I reviewed some documents that and all state and local laws and regulations concerning 19 related to Tennessee. the diversion of opioids. So I'll repeat the question. 20 20 Q. Are you finished? What was done by Mallinckrodt to ensure 21 A. I am. compliance with Tennessee state statutes and local laws 22 Q. And when you looked at those documents, regarding the manufacturing or distribution of opioids? 23 23 did they refresh your recollection in any way? MR. O'CONNOR: Objection to form. 24 A. Refresh my recollection of what? 24 A. I don't know. Page 279 Page 281 1 Q. Whatever the topic was of the document. 1 BY MS. HERZFELD: 2 A. Yes. Q. Do you know if there were any policies in 3 Q. And how many documents that related to 3 place to ensure compliance with Tennessee state and 4 Tennessee would you say you reviewed? 4 local laws regarding the manufacturing or distribution 5 A. Less than five. 5 of opioids? 6 Q. And what types of documents were they? A. I know there were some policies in place 7 ⁷ for some states. I'm not sure whether Tennessee fell MR. O'CONNOR: Object to work product, 8 attorney-client privilege. You can answer at a high 8 within that. 9 level. BY MS. HERZFELD: 10 A. E-mails. 10 Q. Do you know which states you can recall? 11 BY MS. HERZFELD: 11 A. I do not. 12 Q. Who would have been in charge of ensuring Q. Just e-mails? 13 13 compliance with Tennessee state statutes and local laws A. That's all I can recall. 14 Q. And were those e-mails selected for you by regarding the manufacturing and distribution of your counsel, or did you look at some on your own? controlled substances? 15 16 A. Would have been presented to me in 16 A. I don't know. 17 17 preparation from counsel. Q. And your answers are for 2008 forward? 18 Q. And I believe you said you did some 18 A. Yes. preparation outside of your preparation with counsel 19 Q. And who would have been in charge for due earlier; is that correct? 20 diligence to ensure that Tennessee state and local laws 21 21 were being followed with regard to manufacturing or A. Yes. 22 Q. Did you focus any of that preparation time distributing controlled substances in Tennessee? ²³ on the Tennessee litigation? 23 A. I don't know.

24

24

A. No.

Q. Did Mallinckrodt do anything to ensure

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Page 282

- 1 that it was in compliance with Tennessee code annotated
- 2 53-11-302, 303, and 304 concerning the manufacturing of
- 3 controlled substances?
- 4 A. I'm unfamiliar with those.
- 5 Q. And how are you familiar with those?
- 6 A. I said I'm unfamiliar with those.
- 7 Q. So my answer is (sic), here as
- 8 Mallinckrodt's corporate representative today, what did
- 9 Mallinckrodt do, if anything, to ensure compliance with
- 10 TCA 53-11-302, 303, and 304 regarding the manufacturing
- 11 or distribution of controlled substances?
- 12 A. And I'm sorry. What's the question there?
- Q. I'll repeat it.
- 14 A. Okay. Thank you.
- Q. Uh-huh. Did Mallinckrodt do anything to
- 16 ensure that it was in compliance with Tennessee code
- 17 annotated 53-11-303, 302, and 304, concerning the
- 18 manufacturing and distribution of controlled
- 19 substances?
- 20 A. I don't know.
- Q. Did Mallinckrodt do anything to ensure it
- 22 was in compliance with Tennessee code annotated
- 23 53-11-401 regarding the distribution of controlled
- 24 substances?

- Q. Do you recall any of the states that were?
- 2 A. I do not.
- Q. Do you recall what area of the country
- 4 they were in?
 - A. I do not.
- Q. Did Mallinckrodt do anything to monitor
- ⁷ the potential diversion of opioids in Tennessee
- 8 specifically?
- 9 A. It was a national program.
 - Q. But anything specifically about Tennessee?
- 11 A. Not that I'm aware of.
- Q. What about auditing the -- or the
- 13 potential diversion of opioids in Tennessee? Did
- Mallinckrodt do anything specifically for Tennessee in
- ¹⁵ auditing potential diversion of opioids in Tennessee?
- MR. O'CONNOR: Objection to form.
- A. Not that I'm aware of.
- 18 BY MS. HERZFELD:
- Q. What about specific investigations of
- 20 potential diversion of opioids in Tennessee? Did
- 21 Mallinckrodt do anything specific -- strike that. I
 - ² got all caught up on that one.
- 23 Did Mallinckrodt do anything specifically
- 24 to investigate the potential diversion of its opioids

Page 285

Page 283

- 1 A. I don't know.
- Q. Did Mallinckrodt do anything to ensure
- 3 that it was compliance with the Drug Dealer Liability
- 4 Act. Tennessee code annotated 29-38-101?
- 5 A. I don't know.
- 6 Q. What were -- did Mallinckrodt have
- ⁷ policies regarding the detection of potential diversion
- 8 of opioids in Tennessee?
- 9 A. We had a national program.
- Q. And is that the national program that was
- 11 run by Karen Harper?
- 12 A. Yes.
- Q. And she would have been in charge of that?
- 14 A. Yes
- Q. So she would have been the person with the
- 16 most knowledge outside of anyone?
- MR. O'CONNOR: Objection to form.
- MS. HERZFELD: You're right. I'll
- 19 withdraw the question.
- 20 BY MS. HERZFELD:
- Q. Were there any specific policies regarding
- ²² potential diversion of opioids in Tennessee?
- A. Again, there was on some states. I'm not
- 24 sure if Tennessee was one of those states.

- 1 in Tennessee?
- 2 A. Yes.
- Q. What did you do?
- 4 A. I believe there were several
- 5 investigations that were brought to our attention by
- 6 law enforcement, and law enforcement was looking for
- ⁷ assistance, so we provided the assistance.
- 8 Q. Are you finished with your answer?
- 9 A. I am.
- Q. And so you said there were several
- investigations. What were they?
- A. I'm not going to recall all of them. One
- 13 that sticks out is the Sunrise investigation.
- Q. And were you involved in that?
- 15 A. No.
- Q. And what was the extent of the involvement
 - 7 of Tennessee law enforcement in the Sunrise
- 18 investigation, to your knowledge?
- A. To my knowledge, that they had through
- their investigation recovered a bottle of Mallinckrodt
- 21 product, and asked if there was anything that we could
- 22 do to identify where the bottle may have shipped to.
- And so we -- first report we ran was the
- 24 lot number to see which distributors received that lot,

- 1 and then to further assist, they looked to see if there
- ² was any other data in Mallinckrodt's possession that
- 3 might help law enforcement in this case, and they
- 4 looked at chargeback data. And because they had the
- 5 bottle, they were able to get some chargeback data that
- 5 bottle, they were able to get some chargeback data tha
- 6 led to Sunrise.
- Q. What other investigations -- law
- 8 enforcement investigations in Tennessee are you aware
- 9 of?
- 10 A. Specifically, I can't recall at this time.
- 11 But there were -- it's my recollection that there were
- 12 some other law enforcement agencies that had contacted
- 13 us looking for similar information either on a lot
- 14 trace or the amount of active ingredient in one of our
- 15 pills.
- Q. And if I was looking for documents about
- 17 those other investigations -- lot traces or the amount
- 18 of active ingredient in your pills -- where would I
- 19 find those documents?
- A. Either with a search within our DEA
- 21 compliance or our security.
- Q. And you're head of security; is that
- 23 right?
- 24 A. I am.

- 1 something that you need to object -- do you need to
- ² have a privilege there?
- 3 A. Karen Harper.
 - Q. Okay. Karen Harper. Okay. And in that
- ⁵ investigation, does Morristown, Tennessee, ring a bell
- 6 to you?

11

14

- A. It does not.
- Q. So -- but in that investigation having to
- ⁹ do with Sunrise, those drugs were eventually traced
- back to a Dr. Barry Schultz; is that correct?
 - A. That's correct.
- Q. And Barry Schultz was a physician in
- 13 Florida; is that right?
 - A. That's correct.
- Q. And he was running what some would
- 16 characterize as a pill mill; is that right?
- MR. O'CONNOR: Objection. Form.
- A. That's my understanding.
- 19 BY MS. HERZFELD:
- Q. And so in that investigation what they
- 21 learned is that those pills went into the illegal drug
- 22 market along the Oxy Highway; is that right?
- MR. O'CONNOR: Objection to form.
- A. I'm sorry. Who's they that learned that?

Page 289

Page 287

- Q. So have you personally been involved in
- 2 any?
- 3 A. I believe I have.
- 4 Q. And so you think those documents would
- ⁵ either be with DEA compliance group or in the security
- 6 group? They'd be stored there?
- 7 A. Correct.
- 8 Q. And going back to the Sunrise thing you
- 9 said before, was that investigation -- that was before
- 10 your time at Mallinckrodt?
- 11 A. Yes.
- Q. And so how did you learn the information
- 13 about that investigation?
- A. From legal counsel and Karen Harper.
- Q. And when did you learn about it?
- A. I'd say the first time -- can't recall,
- but I'm going to say it was approximately 2014.
- Q. And who told you about it in 2014?
- 19 A. Karen --
- MR. O'CONNOR: I'm going to object to the
- 21 extent it calls for attorney-client privilege
- 22 information.
- 23 BY MS. HERZFELD:
- Q. Did your attorney tell you in 2014

- 1 BY MS. HERZFELD:
- 2 Q. Mallinckrodt learned that?
- A. Oh, okay.
- 4 MR. O'CONNOR: Same objection.
- 5 A. So what did Mallinckrodt learn?
- 6 BY MS. HERZFELD:
- 7 Q. Yes, sir.
- 8 A. Okay.
- 9 Q. Would you like me to say that again?
- 10 A. Yeah, please.
- Q. Sure. And so during the investigation
- with law enforcement, Mallinckrodt learned that those
- 13 pills had come from the pill mill, Dr. Schultz, made it
- 14 into the illegal drug market, up the Oxy Highway; is
- 15 that correct?
- MR. O'CONNOR: Objection. Form.
- A. So define the Oxy Highway, and then --
- 18 BY MS. HERZFELD:
- 19 Q. Up I-75.
 - A. Okay. Yes.
 - Q. And based on that investigation with law
- 22 enforcement in Tennessee, those illegal drugs made it
- 23 into the illegal drug market in Tennessee; is that
- 24 right?

20

21

Page 290 Page 292 1 MR. O'CONNOR: Objection to form. 1 DEA? 2 2 A. That's my understanding. A. Not that I'm aware of. 3 BY MS. HERZFELD: Did Mallinckrodt ever make any reports of Q. And that was Mallinckrodt's understanding suspected diversion to any Tennessee law enforcement? at the time; is that right? A. Not that I'm aware of. MR. O'CONNOR: Same objection. 6 Q. Did Mallinckrodt ever make any reports of ⁷ suspected diversion to federal law enforcement with 7 A. That's correct. 8 jurisdiction over Tennessee, like the U.S. Attorney's 8 BY MS. HERZFELD: Q. And other than those two topics, the office for Tennessee, for example? 10 Sunrise investigation, and then when you said either MR. O'CONNOR: Objection to form. 11 lot traces or amount of active ingredients, can you 11 A. Yeah. So I'm unaware of any suspicious think of any other communication that Mallinckrodt has reports related to Tennessee that were reported to the 13 had with Tennessee law enforcement specifically? 13 DEA. 14 A. I cannot. 14 BY MS. HERZFELD: 15 Q. What about any communication Mallinckrodt Q. And when you say suspicious reports, do 16 has had with Tennessee law enforcement generally? Can 16 you also mean suspected diversion? you recall any? 17 A. Yes, because I'm unaware of any suspected 18 A. No. diversion that Mallinckrodt was aware of taking place 19 Q. Did Mallinckrodt have any policies in Tennessee outside of that Sunrise matter and the 20 regarding the disclosure of suspicious orders in doctor that was located in Florida. Tennessee to the DEA? 21 Q. And if there was suspected diversion in 22 A. I'm unaware of any suspicious orders to 22 Tennessee, who would have been in charge of reporting 23 Tennessee. that to Tennessee law enforcement? 24 Q. And when you say unaware of any suspicious A. Security. Page 291 Page 293 1 orders to Tennessee, do you mean shipped or meant for Q. And security would have been you? A. Currently would be me, but -- time frame; Tennessee? 3 MR. O'CONNOR: Objection to form. ³ right? So June 2012 on, law enforcement contact -- I 4 was the main law enforcement contact for Mallinckrodt 4 BY MS. HERZFELD: Well, I guess what do you mean when you 5 and had contact with federal, state, and local law 6 say -enforcement across the country. 7 Yeah. I mean --And before you it would have been Mr. 8 Ratliff? 8 -- you're unaware of any suspicious 9 orders to Tennessee? What do you mean by that? A. Correct. Q. Did Mallinckrodt ever report to the DEA 10 A. Yeah. So I'm unaware that there were any 10 11 suspicious orders reported to DEA that were intended 11 that it was limiting sales of anyone in Tennessee that 12 they suspected of suspicious orders? for Tennessee. A. So I can't recall any sales of our 13 Q. And so to your knowledge there weren't any 13 reports of suspicious orders to DEA about Tennessee? products to distributors in Tennessee. So can you 15 A. Right. 15 restate -- just repeat your question? Q. Sure. Sure. I'll kind of rephrase it. 16 Q. And who would have been in charge of 16 17 making those reports if they had occurred? I guess I'm wondering if you know if 18 A. DEA compliance. Mallinckrodt ever reported to the DEA of halting of 19 Q. And who is head of DEA compliance? sales to anyone involved in suspicious orders in 20 A. Karen Harper. 20 Tennessee. 21 Q. What about any reports of suspected 21 A. No.

22

22 diversion to the DEA -- I'm going to back up again.

24 any reports of suspected diversion in Tennessee to the

What about -- did Mallinckrodt ever make

Q. I'm going to back up a little bit, too.

24 distributors. Also based on chargeback data. You had

23 And when I'm saying sales, I don't just mean to the

- ¹ access to chargeback data at Mallinckrodt; is that
- ² correct?
- 3 MR. O'CONNOR: Objection to form.
- 4 A. But those weren't our sales. The sales
- ⁵ were from -- those sales to the pharmacies would have
- 6 been from the distributors.
- ⁷ BY MS. HERZFELD:
- 8 Q. And I --
- 9 A. Did we have chargeback data? Yes. Those
- 10 were retroactive.
- Q. So I'm going to back up my questions a
- 12 little bit.
- So to your knowledge there weren't any
- 14 distributors in Tennessee that Mallinckrodt was selling
- ¹⁵ opioid products to? Is that your testimony?
- 16 A. That I can recall. Correct.
- Q. And so I shouldn't have said sales,
- 18 perhaps.
- So when we're talking about the shipping
- 20 of Mallinckrodt opioids that end up to people in
- 21 Tennessee, Mallinckrodt would have some of that
- ²² information via chargeback data; is that correct?
- A. Correct.
- MR. O'CONNOR: Objection to form.

Page 296

Page 297

- Q. And so I guess my question is a little bit more basic.
- 3 A. Okay.
 - Q. Mallinckrodt could do chargeback
- ⁵ restrictions; is that right?
- 6 A. Yes.
- Q. And chargeback restrictions would then
- ⁸ give a financial incentive for the distributor not to
- ⁹ do business with that particular pharmacy; is that
- 10 correct?
- A. Can you repeat that question? Because I
- 12 think --

13

14

Page 295

- Q. Do I have it backwards?
- A. I think so.
- Q. So the chargeback restriction would give a
- ¹⁶ financial incentive for the distributor not to do
- business with that pharmacy; is that right?
- A. I'm wondering if you're still getting that
- 19 wrong. A financial incentive not to sell?
- Q. Okay. I'm going to back up.
- A. Okay.
- Q. Explain to me your understanding of a
- ²³ chargeback. Let's start there.
- 24 A. So it's --

1 BY MS. HERZFELD:

- Q. And based on that chargeback data,
- 3 Mallinckrodt would sometimes put different pharmacies
- 4 on chargeback restrictions; is that right?
- 5 A. That's correct.
- 6 Q. And so based on those chargeback
- 7 restrictions, did Mallinckrodt ever report the limiting
- 8 of the ability to process chargebacks for pharmacies in
- 9 Tennessee?
- MR. O'CONNOR: Objection to form.
- 11 A. So I'm sorry. I'm not sure I understand
- 12 that question.
- 13 BY MS. HERZFELD:
- 14 Q. Sure.
- A. So are you asking me did we restrict a
- 16 pharmacy in Tennessee? Is that the question?
- 17 Q. It's not.
- 18 A. Okay.
- Q. But sure, do you know if you did?
- A. I don't recall, but I know the records
- 21 were provided of all the pharmacies that were
- ²² chargeback restricted.
- Q. In Tennessee?
- A. For the entire country.

- MR. O'CONNOR: Objection to scope.
- A. It's a contractual relationship between
- 3 Mallinckrodt and its customers, distributors and
- 4 wholesalers. After they've bought the product, if they
- ⁵ sell it to one of their customers for less than what
- 6 they bought it, they can charge back that difference to
- 7 us.
- 8 BY MS. HERZFELD:
- 9 Q. And if Mallinckrodt put somebody on a
- 10 chargeback restriction, what is the impact that that
- 11 has for the wholesaler?
- MR. O'CONNOR: Objection to form.
- A. It could be a financial disincentive,
- 14 because if they continue to sell to the pharmacy they
- would not be made whole.
- 16 BY MS. HERZFELD:
- Q. So that is one way that Mallinckrodt would
- deal with its customers' customers, is chargeback
- 19 restrictions; is that right?
- MR. O'CONNOR: Objection to form.
- A. One way Mallinckrodt could deal with its
- 22 customer's customer, by chargeback restricting them?
- 23 BY MS. HERZFELD:
- Q. Yes, sir.

A. Yes.

- Q. Was there ever anything between chargeback
- ³ restrictions, like a chargeback limiting?
- 4 MR. O'CONNOR: Objection to form.
- 5 A. I don't even know what that means. I'm
- 6 sorry.

1

- ⁷ BY MS. HERZFELD:
- 8 Q. So did you ever -- did Mallinckrodt ever
- 9 attempt to limit the sale of or the distribution of --
- 10 I'm going to back up. Strike that. Start over.
- Did Mallinckrodt ever try to limit the
- 12 volume of its products, its opioid products, to
- 13 particular pharmacies?
- A. So we didn't sell to the pharmacies; the
- 15 distributors did.
- 16 Q. I understand.
- 17 A. Okay.
- Q. But you could disincentivize the
- 19 distributors from doing business with pharmacies by
- ²⁰ implementing chargeback restrictions.
- That's what we've established; right?
- A. We wouldn't know which pharmacies the
- 23 distributors were selling to unless we looked at the
- 24 chargeback data.

- e 298
 - 1 that's all you would do if you had a suspicion that a
 - 2 pharmacy based on information that you had might be
 - 3 engaged in diversion?
 - Did I understand that correctly?
 - MR. O'CONNOR: Objection to form.
 - 6 A. Yeah, could you restate that one more
 - 7 time?
 - 8 BY MS. HERZFELD:
 - Q. Sure. So I think from your explanation
 - that you just gave me is you said if you, based on the
 - 11 information Mallinckrodt had, suspected that a pharmacy
 - 12 might be engaged in diversion, you would notify the
 - distributor that you would be placing that pharmacy on
 - 14 chargeback restriction.
 - Did I understand that correctly?
 - A. That's correct. We would notify the DEA
 - 17 and all distributors that -- so you might be the only
 - 18 distributor providing product, but we would notify the
 - 19 DEA and all distributors that we were chargeback
 - 20 restricting that pharmacy.
 - Q. And when did that begin?
 - A. The earliest I recall was 2011.
 - Q. And was that notifying the DEA in 2011 or

Page 301

24 notifying all the distributors in 2011?

Page 299

- Q. Okay, but that's not my question.
- A. Okay. Then I'm confused by what you're
- 3 trying to ask me on this.
- 4 Q. So what I'm say --
- 5 A. Because we sell to distributors and the
- 6 wholesalers, and you're asking me to reduce product to
- ⁷ the pharmacy that I'm not selling to. That's how I
- 8 understood your question.
- 9 Q. So what do you understand the purpose of
- 10 chargeback restrictions to be?
- 11 A. So if we think there's a potential for
- 12 diversion based on the information that we've seen,
- 13 then we restrict the chargebacks, advising the
- distributors that we have an issue with this pharmacy.
- So if they want to continue to sell, they,
- 16 the distributors or wholesalers, that's on them, but
- we're not going to give them the chargeback. So the
- 18 restriction comes from we not paying the distributors
- 19 and the wholesalers that difference.
- That's the piece there, and it has nothing
- 21 to do with the pharmacy, because we won't know which
- ²² pharmacy that is until weeks or a month or longer
- 23 later.

24

Q. And so other than chargeback restrictions,

A. Both.

- 2 MR. O'CONNOR: Objection.
- ³ BY MS. HERZFELD:
- 4 Q. And so I guess my question is, other than
- 5 that process which you've just explained, was there
- 6 anything else you would do if you suspected a potential
- ⁷ pharmacy was engaging in diversion?
- 8 A. If we did suspect, we'd contact law
- 9 enforcement.

11

- Q. And which law enforcement? The DEA?
 - A. DEA, the applicable state or local agency.
- Q. And where would I find records of those
- 13 contacts with state or local agencies?
 - A. Well, first of all, you would have -- if
- the record existed, it would be in security's files.
- 16 But I'm not saying that there are any that exist.
- Q. Is there a reason that there wouldn't be
- 18 ones that exist?
- A. Yeah, because we didn't have any
- 20 information that a particular pharmacy was involved in
- 21 diversion.
- Q. Can you recall a time when you had
- 23 information that a particular pharmacy was involved in
- 24 diversion?

| | <u> </u> | | |
|--|---|--|---|
| | Page 302 | | Page 304 |
| 1 | | 1 | 11. |
| | pharmacies that I had concern about, and I notified the | 2 | C |
| 3 | DEA on that. | 3 | MR. O'CONNOR: Objection to scope. |
| 4 | Q. Is that all? | 4 | A. I mean, I'm uncertain, but it says |
| 5 | A. Yes. | 5 | department, legal, and stuff, and the purpose and the |
| 6 | Q. Does Mallinckrodt to your knowledge have | 6 | file path. I mean, it looks like folders within a |
| 7 | , r | 7 | |
| 8 | that are specific to Tennessee? | 8 | BY MS. HERZFELD: |
| 9 | A. No, it's a national program. | 9 | Q. And do you have any way of knowing if this |
| 10 | Q. I'm going to show you what we will mark | 10 | is a complete listing of the files in the computer |
| 11 | here as Plaintiff's Exhibit 31. | 11 | system? |
| 12 | [Exhibit Mallinckrodt-Gillies-031 | 12 | MR. O'CONNOR: Objection to scope. |
| 13 | marked for identification.] | 13 | A. I have no idea. |
| 14 | Q. I don't like to use the ELMO. | 14 | BY MS. HERZFELD: |
| 15 | A. Really? | 15 | Q. And when you say that documents would be |
| 16 | Q. Do you want me to use I can use it if | 16 | in security, for example |
| 17 | , | 17 | A. Uh-huh. |
| 18 | Okay. Here. Ooh, it's really small. Yeah, I can see | 18 | Q there's a security folder at |
| 19 | why. | 19 | Mallinckrodt? |
| 20 | THE VIDEOGRAPHER: Can you see? | 20 | A. Yes. |
| 21 | MS. HERZFELD: Can you see? How's that? | 21 | Q. And that would look something like one of |
| 22 | THE VIDEOGRAPHER: Here you go. | 22 | these? It's not like a filing cabinet; it's like a |
| 23 | BY MS. HERZFELD: | 23 | computer path? |
| 24 | Q. That's good. Is that better? | 24 | A. That's correct. |
| | Page 303 | | Page 305 |
| 1 | _ | 1 | |
| 2 | | 2 | |
| 3 | gets. | 3 | Q. Thank you. Okay. Moving on to Exhibit |
| 4 | A. Okay. | 4 | 32. |
| 5 | BY MS. HERZFELD: | 5 | [Exhibit Mallinckrodt-Gillies-032 |
| 6 | Q. When we all get over a certain age, it | 6 | marked for identification.] |
| 7 | makes it difficult to see. Okay. Okay. If you'll | 7 | Q. This one's a little bit easier to see. |
| 8 | take a look at this document. | 8 | Okay. |
| 9 | A. I'm not going to be able to see it here. | 9 | A. Okay. |
| 10 | So can you just | 10 | Q. Have you seen this document before? |
| | | | |
| 11 | Q. Just you can see it from there. | 11 | A. I believe I have. |
| 11 12 | Q. Just you can see it from there.A. Okay. | 11 12 | - · |
| | | | A. I believe I have.Q. And it looks like at the bottom it says |
| 12 13 | A. Okay. | 12 13 | A. I believe I have.Q. And it looks like at the bottom it says |
| 12 13 14 | A. Okay.Q. Yeah. Okay. I'm just going to show you | 12 13 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from |
| 12 13 14 | A. Okay.Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been | 12 13 14 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? |
| 12 13 14 15 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. | 12 13 14 15 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about |
| 12 13 14 15 16 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it | 12 13 14 15 16 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about |
| 12 13 14 15 16 17 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it | 12 13 14 15 16 17 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the |
| 12 13 14 15 16 17 18 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it appears to be? A. I mean, it appears to be a search of files | 12 13 14 15 16 17 18 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the years. Is that right? |
| 12 13 14 15 16 17 18 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it appears to be? A. I mean, it appears to be a search of files | 12 13 14 15 16 17 18 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the years. Is that right? A. Yes. Q. And did you ever attend those DEA |
| 12 13 14 15 16 17 18 19 20 21 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it appears to be? A. I mean, it appears to be a search of files that they're providing. | 12 13 14 15 16 17 18 19 20 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the years. Is that right? A. Yes. Q. And did you ever attend those DEA |
| 12 13 14 15 16 17 18 19 20 21 22 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it appears to be? A. I mean, it appears to be a search of files that they're providing. Q. And so when I look at this document, it | 12 13 14 15 16 17 18 19 20 21 22 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the years. Is that right? A. Yes. Q. And did you ever attend those DEA conferences? |
| 122 133 144 155 166 177 188 199 200 211 222 233 | A. Okay. Q. Yeah. Okay. I'm just going to show you this document here, and this is a document that's been produced to us in discovery. A. Okay. Q. Can you tell from this document what it appears to be? A. I mean, it appears to be a search of files that they're providing. Q. And so when I look at this document, it looks to me like it's a printout of all the different | 12 13 14 15 16 17 18 19 20 21 22 | A. I believe I have. Q. And it looks like at the bottom it says it's the DEA distributor conference PowerPoint from September 23rd, 2015. Is that correct? A. Yes. Q. And I think you were talking before about different DEA conferences that occur throughout the years. Is that right? A. Yes. Q. And did you ever attend those DEA conferences? A. Put on by DEA? No. Put on by others? |

| | | 5 1 | | |
|-----|----|---|-------|--|
| | | Page 306 | | Page 308 |
| | | those conferences from DEA, they would bring back | | that right? |
| | | information to the team; is that right? | 2 | A. Correct. |
| | 3 | A. That's right. | 3 | Q. And does there appear to be more darkened |
| | 4 | Q. And is that how this PowerPoint made it | 4 | shades on the 2009 than there were on the 2008? |
| | 5 | back from this conference to Mallinckrodt? | 5 | MR. O'CONNOR: Objection to form. |
| | 6 | A. I don't know how it made it back, so | 6 | A. Yes. |
| | 7 | Q. But you've seen it before? | 7 | BY MS. HERZFELD: |
| | 8 | A. I believe I have. | 8 | Q. If you'll flip with me to the next page. |
| | 9 | Q. If you'll flip through with me here. | 9 | If you could give me the title there, please. |
| | 10 | A. Okay. | 10 | A. 2010 Tennessee opioid prescriptions. |
| | 11 | Q. To there aren't really any pages on it. | 11 | Q. And this also shows the prescription rate |
| | 12 | A. Okay. | 12 | per hundred population, with the darkest number being |
| | 13 | Q. There aren't page numbers. It's about | 13 | the highest; is that correct? |
| | | _ | 14 | A. Correct. |
| | 15 | the first map. If you'll take a look at that for me, | 15 | Q. And does 2010's map look darker in some |
| | | please. | 16 | sections than 2009? |
| | 17 | A. Yes. | 17 | MR. O'CONNOR: Objection to form. |
| | 18 | Q. You see where I'm at? | 18 | A. Yes. |
| | 19 | A. Yes. | 19 | BY MS. HERZFELD: |
| | 20 | Q. Could you please tell me what the title of | 20 | Q. If you'll flip with me to the next page, |
| | | this map is? | 21 22 | please. What is the title of that page? |
| | 22 | A. 2007 Tennessee opioid prescriptions. | | A. 2011 Tennessee opioid prescriptions. |
| | 23 | Q. And that's showing prescription rate per | 23 | Q. And this it says here is a map of |
| | 24 | hundred population; is that right? | 24 | Tennessee, with the darkest colors being the highest |
| | | Page 307 | | Page 309 |
| | 1 | A. Yes. | 1 | rate of prescription per hundred population; is that |
| | 2 | Q. Flip with me to the next page, please. | 2 | correct? |
| | 3 | Could you tell me the title there? | 3 | A. Correct. |
| | 4 | A. 2008 Tennessee opioid prescriptions. | 4 | Q. And would you agree that the 2011 map |
| | 5 | Q. And that's also showing prescription rates | 5 | looks darker than the 2010 map? |
| | 6 | per hundred population; is that right? | 6 | MR. O'CONNOR: Objection to form. |
| | 7 | A. Yes. | 7 | A. Yes. |
| | 8 | Q. And the highest prescription rate is the | 8 | BY MS. HERZFELD: |
| | 9 | darkest color; is that right? | 9 | Q. And if you look at the 2007 map compared |
| | 10 | A. Yes. | 10 | to the 2011 map. |
| | 11 | Q. And from the 2007 page to 2008 page, do | 11 | Based on these two documents, would you |
| | 12 | you agree that there are more darkened colors in 2008 | 12 | say the prescription rate for opioids per hundred |
| | 13 | than there were in 2007? | 13 | population in Tennessee went up? |
| | 14 | MR. O'CONNOR: Objection to form. | 14 | A. Yes. |
| | 15 | A. Yes. | 15 | Q. If you'll flip with me to the next page, |
| | 16 | BY MS. HERZFELD: | 16 | the one at the bottom that says 607272. Could you read |
| | 17 | Q. If you'll flip with me to the next page, | 17 | the title of that page for me, please? |
| | 18 | please. Could you read the title there for me, please? | 18 | A. Painkiller prescriptions by state. |
| | 19 | A. 2009 Tennessee opioid prescriptions. | 19 | Q. Okay. Could you read the rest of the |
| | 20 | Q. And that also is a prescription rate per | 20 | slide for me here? |
| | 21 | | 21 | A. In 2012, southern states had the most per |
| | 22 | A. Correct. | 22 | person. The top three states were Alabama, Tennessee, |
| | 23 | Q. And the darkened number is the highest | 23 | and West Virginia. Alabama, 143 per hundred people. |
| - 1 | | | | |
| | 24 | number of prescription rates per hundred population; is | 24 | Tennessee, 143 per hundred people. West Virginia, 138 |

| se | Ή | l:17-md-02804-DA ighly confider | P_Doc #: 3013-11_Filed htial *- Subject to | 1 | 2/18/1 urth | 9 80 of 85 PageID#: 446071 er Confidential#:ty Review |
|-----|-----|------------------------------------|--|----------|----------------|--|
| Γ | | | Page 310 | | | Page 312 |
| | 1 | per hundred people. Lo | west, Hawaii, 52 per hundred | 1 | Q. | Where it says crime? |
| | | people. | west, manufect per manufect | 2 | A. | Drug-related crimes have increased 33 |
| | 3 | | with me to the next page, | 3 | | from 2005 to 2012. Lost productivity, |
| | 4 | please. Read the title of | | | _ | tion drug abuse cost was estimated at \$143 |
| | 5 | A. Tennessee pair | | | - | in 2008. Adjusted for inflation, it's now \$160 |
| | 6 | - | s that there are 307 | | million. | • |
| | 7 | certified clinics within 7 | Tennessee; is that right? | 7 | Q. | And if you'll switch with me then to the |
| | 8 | A. That's what it s | _ | 8 | next tl | he page at the bottom that's 7277. Could you |
| | 9 | | t down by counties; is that | 9 | | title of that page for me, please? |
| | 10 | right? | • | 10 | A. | Unlawful distribution. |
| | 11 | A. Yes. | | 11 | Q. | And the first line it says is |
| | 12 | Q. If you'll flip w | ith me to the next page, | 12 | inapprop | priate or overprescribing. Would you agree that |
| | 13 | 724 7274. Okay. If y | ou could tell me what the | 13 | that is u | nlawful distribution of opioids? |
| | 14 | title of this page is, plea | se. | 14 | | MR. O'CONNOR: Objection to form. |
| | 15 | A. Tennessee top | 10 controlled substances, | 15 | A. | If there wasn't a legitimate medical |
| | 16 | 2014. | | 16 | purpose. | |
| | 17 | Q. And what is th | e top controlled substance | 17 | BY MS. | HERZFELD: |
| | 18 | for Tennessee in 2014, a | according to this chart? | 18 | Q. | What about knowledge of redistribution? |
| | 19 | A. Hydrocodone | products. | 19 | Would t | hat constitute unlawful distribution of opioids? |
| | 20 | Q. And the second | d? | 20 | | MR. O'CONNOR: Objection to form. |
| | 21 | A. Alprazolam. | | 21 | A. | So just so that I'm clear, what are we |
| | 22 | Q. And the third? | | 22 | saying k | nowledge of redistribution is? |
| | 23 | A. Oxycodone. | | 23 | BY MS. | HERZFELD: |
| | 24 | Q. And does Mall | inckrodt produce oxycodone? | 24 | Q. | Knowledge of redistribution of an opioid |
| ŀ | | | Page 311 | | | Page 313 |
| | 1 | A. Yes. | | 1 | without | a legitimate medical purpose. |
| | 2 | Q. And does Mallin | nckrodt produce hydrocodone? | 2 | | MR. O'CONNOR: Objection to form. Same |
| | 3 | A. Yes. | | 3 | objectio | n. |
| | 4 | Q. If you'll switch to | to the next one for me, | 4 | A. | So somebody's redistributing the product |
| | 5 | please, the one at the bott | om that says 7275. Read the | 5 | for a no | nmedical purpose or a scientific purpose; |
| | 6 | top of the page for me, pl | ease. | 6 | right? | |
| | 7 | A. Impact in Tenne | essee. | 7 | BY MS | . HERZFELD: |
| | 8 | Q. And then what i | s the next line that starts | 8 | Q. | Or a drug abuse purpose? |
| | 9 | with deaths? | | 9 | A. | Or doing it for a drug abuse purpose? |
| | 10 | A. Deaths. Over 1, | 000 people are dying from | 10 | Q. | Yes, sir. |
| | 11 | in the state every year. | | 11 | A. | Okay. |
| | 12 | Q. And the next on | e that starts with | 12 | Q. | Would you consider that to be unlawful |
| | 13 | children? | | 13 | distribut | tion of an opioid product? |
| | 14 | A. Children. 50 pe | rcent of the children in | 14 | | MR. O'CONNOR: Objection. Form. |
| | 15 | DCS care are there becau | se of parental drug abuse. | 15 | A. | It would be diversion of the product. |
| | 16 | Over the past decade, the | re's been a tenfold rise in | 16 | BY MS | . HERZFELD: |
| | 17 | the incidence of babies bo | orn with neonatal abstinence | 17 | Q. | And is diversion of the product unlawful? |
| | 18 | syndrome. | | 18 | A. | And it could be. |
| | 19 | | t says health care costs? | 19 | Q. | Lax or careless prescription practices. |
| | 20 | A. Health care cost | | 20 | | nat be indicative of unlawful distribution? |
| | 21 | | 40 percent from 2005 to 2010. | 21 | | MR. O'CONNOR: Objection to form. |
| | | = | ng drug treatment to Tennessee | 22 | | I don't know what that relates to, but it |
| | 23 | drug abusers living below | the poverty line is \$28 | 23 | could be | e. |
| - 1 | 0.4 | | I | ~ 4 | D 37 3 40 | HEDZEELD |

24 million.

24 BY MS. HERZFELD:

| se | H | :17-md-02804-DAP Doc#: 3013-11 Filed | : 1 | 2/18/19 81 of 85. PageID #: 446072 Further Confidential ty Review |
|----|----|---|-----|--|
| | | Page 314 | | Page 316 |
| | 1 | Q. What about people who are doctor shoppers? | 1 | A. I'll take your comment that that's |
| | 2 | Could that indicate unlawful distribution? | 2 | accurate. |
| | 3 | MR. O'CONNOR: Objection to form. | 3 | BY MS. HERZFELD: |
| | 4 | A. It could be somebody that's involved in | 4 | Q. Is that what the page shows? |
| | 5 | the illicit drug trade. | 5 | A. It shows names, ages, and then I'm making |
| | 6 | BY MS. HERZFELD: | 6 | the assumption that that's their sentencing and how it |
| | 7 | Q. And prescription rings would be | 7 | either occurred through a plea or trial. |
| | 8 | prescription drug rings. That would be an unlawful | 8 | Q. So based on these documents that we've |
| | 9 | distribution of opioids; is that correct? | 9 | looked at, was Mallinckrodt aware that there was an |
| 1 | 10 | MR. O'CONNOR: Objection to form. | 10 | opioid crisis in Tennessee? |
| 1 | 11 | A. Yes. | 11 | MR. O'CONNOR: Objection to form. |
| 1 | 12 | BY MS. HERZFELD: | 12 | A. As I've stated earlier, Mallinckrodt |
| 1 | 13 | Q. You can switch with me on oops. Losing | 13 | became aware of the scope of the opioid crisis after |
| 1 | 14 | myself here. Okay. If you'll switch with me to the | 14 | our meeting with the DEA in August of 2011. |
| 1 | 15 | one at the bottom that says 7286. It says United | 15 | BY MS. HERZFELD: |
| 1 | 16 | States versus Lang. Do you see that? | 16 | Q. And Mallinckrodt was aware that there was |
| 1 | 17 | A. Yes. | 17 | an opioid crisis in Tennessee as well; is that correct? |
| 1 | 18 | Q. And this says Superior One Medical Clinic. | 18 | MR. O'CONNOR: Objection to form. |
| 1 | 19 | | 19 | A. I don't know that. |
| 2 | 20 | located? | 20 | BY MS. HERZFELD: |
| 2 | 21 | A. I do not. | 21 | Q. If you'll switch with me to the page here |
| 2 | 22 | Q. If I told you it was in Tennessee, would | 22 | in this one last one here, 7310, the second to third |
| 2 | 23 | - | | back. Okay. Could you read the title of that page for |
| 2 | 24 | MR. O'CONNOR: Objection to form. | | me, please? |
| | | Page 315 | | Page 317 |
| | 1 | A. I don't think you would mislead me. | 1 | A. Red flags. |
| | 2 | BY MS. HERZFELD: | 2 | Q. And red flags that are indicated by this |
| | 3 | Q. I'm going to just flip through this to | 1 | DEA PowerPoint here the first one is complaints. |
| | | make this a little bit quicker. Okay. On the one at | | Did Mallinckrodt consider complaints to be a red flag |
| | | the bottom that says 7288. Okay. Can you read me the | 5 | of diversion? |
| | 6 | title of that document, please? | 6 | MR. O'CONNOR: Objection to form. |
| | 7 | A. Oxycodone's street value is based on | 7 | A. Mallinckrodt considered certain red flags. |
| | 8 | prescriptions. | 8 | I'm not sure what the complaint is referencing here on |
| | 9 | Q. Are you aware that there is a street value | 9 | this page. So |
| 1 | 10 | for oxycodone? | 10 | BY MS. HERZFELD: |
| 1 | 11 | MR. O'CONNOR: Objection to form. | 11 | Q. I'll rephrase the question. When |
| 1 | 12 | A. Yes. | 12 | Mallinckrodt was looking for red flags of diversion, |
| 1 | 13 | BY MS. HERZFELD: | 13 | would Mallinckrodt look for complaints about a |
| 1 | 14 | Q. And if you'll switch with me almost all | 14 | particular location? |
| 1 | 15 | the way here to the back. The one that's 7309. My | 15 | A. So |
| 1 | 16 | apologies. Okay. Could you read the top of that title | 16 | MR. O'CONNOR: Objection to form. |
| - | | c | 117 | A G 1:4 : 4 1 0 |

18 A. More east Tennessee pill defendants. 19

Q. And this indicates -- one, two, three,

²⁰ four, five, six, seven, eight, nine, 10, 11, 12 -- 12

21 people who pled guilty or were found guilty of some

22 crime involving pills in east Tennessee, according to

23 this chart; is that correct?

17 for me?

24 MR. O'CONNOR: Objection. 17 A. Complaints against a pharmacy?

18 BY MS. HERZFELD:

19 Sure.

20 Yes. A.

21 Q. Complaints about a doctor?

22 Yes.

23 Q. Complaints about there being a pill mill

24 someplace?

MR. O'CONNOR: Objection to form.

2 A. Yes.

³ BY MS. HERZFELD:

- Q. What about form of payment? Is form of
- 5 payment something that Mallinckrodt would look at?
- 6 A. Yes.
- Q. What about the types of customers? Is
- 8 that something Mallinckrodt would look at?
- 9 A. So again, our customers are the
- 10 distributors and the wholesalers, so I'm assuming on
- 11 this page this is talking about customers to the
- 12 pharmacy.
- Do you know? Because I don't know what
- 14 types of customers here, but our customers are the
- 15 wholesalers and distributors. So -- I don't know how
- 16 they're defining types of customers here, so it's hard
- 17 for me to answer that question.
- Q. So when we said before form of payment is
- 19 something that Mallinckrodt would look at to indicate
- 0 diversion, is that form of payment of the distributor?
- A. No, in that case, working through the
- 22 distributors and the wholesalers, we would learn
- 23 whether there's a high percentage of cash being paid
- ²⁴ for products. So from that perspective, that's one of

- 1 sales? Is that one of the routine things Mallinckrodt
- ² would look for through its wholesalers or distributors?
- 3 MR. O'CONNOR: Objection to form.
 - A. So again, our sales are to the
- 5 distributors and wholesalers. In our chargeback
- 6 review, if we saw an increase in sales, we would ask
- ⁷ for an explanation from the distributors or the
- 8 wholesalers.
- 9 BY MS. HERZFELD:
- Q. And that's how the process goes now?
- 11 A. That is how the process is, yes.
- Q. And is that how the process has been the
- 13 entire time you've been at Mallinckrodt?
- 14 A. Yes.
- Q. And when you would communicate with
- 16 Mallinckrodt about some of these types of things -- you
- 17 said you would get that information through your
- distributors or wholesalers.
 - When they gave you that information, would

Page 321

- 20 Mallinckrodt do anything to verify that information, or
- 21 would you just accept what your wholesalers or
- distributors tell you?
- MR. O'CONNOR: Objection to form.
 - A. So can you repeat that question?

Page 319

24

- 1 the red flags we would be looking for.
- Q. And would you look through the
- 3 distributors or wholesalers for the types of customers?
- 4 A. No
- 5 Q. Would you look through the distributors or
- 6 wholesalers for the type of location?
- 7 MR. O'CONNOR: Object to form.
- 8 A. So if the distributor or wholesaler --
- 9 actually, if Mallinckrodt became concerned about a
- 10 pharmacy, we would do some research on the location of
- 11 that pharmacy.
- But again, I don't know what they mean by
- 13 type of location, so I don't know how to fully reply to
- 14 that question without knowing what he meant or she
- meant when she wrote type of location.
- 16 BY MS. HERZFELD:
- Q. Is that -- is the type of location for
- where a pharmacy is located, is that something that
- 19 Mallinckrodt would request information of routinely
- 20 from his wholesalers or distributors?
- 21 A. No.
- MR. O'CONNOR: Objection to form.
- 23 BY MS. HERZFELD:
- Q. What about an unexplained increase in

- 1 BY MS. HERZFELD:
- 2 Q. Sure.
- A. Just so I completely understand it. Yeah.
- 4 Q. Yeah. I'm going to try not to go through
- 5 the whole list, because --
- 6 A. Okay.
- 7 Q. But you had said before that when we were
- 8 talking about some of these questions --
- 9 A. Uh-huh.
- Q. -- you would try to -- Mallinckrodt would
- 11 try to get that information through its wholesalers or
- 12 distributors in some circumstances. Did I characterize
- 13 your testimony fairly?
- 14 A. Yeah, if we became aware of a pharmacy
- 15 that we should be concerned about. Okay.
- Q. But absent somebody making you aware of
 - 7 something you should -- Mallinckrodt would be concerned
- 18 about with a particular pharmacy, you didn't routinely
- 19 check on these things for your customer's customer; is
- 20 that right?

24

- MR. O'CONNOR: Objection to form.
- A. That's correct.
- 23 BY MS. HERZFELD:
 - Q. So I guess my question is, if you had a

1

10

Page 322

- 1 concern about a particular pharmacy -- for example,
- 2 because of an increased amount of sales -- and you
- ³ reached out to your distributor, your wholesaler
- 4 person, as you've said that you would, you would ask
- 5 them for an explanation?
- A. That's right.
- ⁷ Q. And then they would come back to you with
- 8 an explanation?
- 9 A. That's correct.
- Q. Would you do any additional investigation
- 11 to verify that the explanation they gave you was
- 12 accurate, or would you --
- 13 A. No.
- MR. O'CONNOR: Objection to form.
- A. We worked with these distributors and
- 16 wholesalers, and I trusted what they were telling me.
- 17 BY MS. HERZFELD:
- Q. Okay. That's my last question on this
- 19 document.
- 20 A. Okay.
- MR. KO: Tricia, I hate to interrupt. Can
- 22 we go off the record for just one minute?
- MS. HERZFELD: Sure.
- THE VIDEOGRAPHER: We are going off the

- Q. And other than what we've discussed with
- 2 your previous interaction with law enforcement in
- 3 Tennessee, are you aware of any other inquiries from
- 4 law enforcement in Tennessee about opioid abuse in
- 5 Tennessee?
 - A. Not that I can recall.
 - Q. And has Mallinckrodt communicated at all
- 8 with the Tennessee Attorney General about opioid abuse
- 9 or diversion in Tennessee?
 - I don't know about Tennessee.
- Q. Do you know who the Attorney General of
- 12 Tennessee is right now?
- 13 A. I do not.
- Q. Does the name Herb Slatery ring any bells
- 15 to you?
- 16 A. I'm sorry. It does not.
- Q. What about a gentleman named Bob Cooper?
- 18 Kind of a general name, but Bob Cooper as the Tennessee
- 19 Attorney General, does that mean anything to you?
- 20 A. No.
- Q. Have you personally communicated with
- 22 anyone at the Tennessee Attorney General's office about
- 23 the abuse or diversion of opioids in Tennessee?
- 24 A. No.

Page 323

- ¹ record at 5:47 PM.
- 2 [A brief recess was taken.]
- 3 THE VIDEOGRAPHER: We are back on the
- 4 record at 6:02 PM.
- 5 BY MS. HERZFELD:
- 6 Q. Okay, Mr. Gillies. We're back on the
- ⁷ record after a short break. I just have a few more
- 8 questions for you, and hopefully they'll be pretty
- ⁹ quick.
- When you were talking earlier about the
- 11 role of wholesalers and distributors in the supply
- 12 chain and the policies that you have, along with those
- 13 for the distribution of opioids, are those different in
- 14 any way for Tennessee than they are nationally?
- 15 A. No.
- MR. O'CONNOR: Objection to form.
- 17 BY MS. HERZFELD:
- Q. Have you been involved -- strike that.
- Have you -- are you aware of any formal or
- ²⁰ informal investigations about opioid distribution
- 21 within Tennessee?
- A. Outside what we've discussed?
- Q. Yes, sir.
- 24 A. No.

- Q. I think there was a topic about online
- ² pharmacies. Do you know if any online pharmacies

Page 325

- 3 shipped any Mallinckrodt products to Tennessee?
- 4 A. I'm not aware of any.
- 5 Q. Do you know if online pharmacies' ordering
- 6 of Mallinckrodt products had any connection to
- 7 Tennessee in any way?
- 8 MR. O'CONNOR: Objection to form.
- 9 A. I'm sorry. Could you restate that one
- 10 more time? Or repeat it, actually, not restate it.
- 11 BY MS. HERZFELD:
- Q. Sure. Do you know if any online
- 13 pharmacies' ordering of Mallinckrodt products have any
- 14 connection to Tennessee?
- 15 A. I do not.
- MR. O'CONNOR: Objection.
- MS. HERZFELD: Okay. I don't have any
- 18 more questions for you.
- 19 A. Okay.
 - MS. HERZFELD: Thank you.
- 21 A. Thank you.
- MR. O'CONNOR: Any questions from anybody
- 23 else?

20

MS. HARMON: No.

| | Page 326 | | Page 328 |
|----|---|----|---|
| 1 | MR. O'CONNOR: I just have a very short, | 1 | CERTIFICATE |
| 2 | very short list of questions. | 2 | |
| 3 | MS. HERZFELD: Like your two minutes. | 3 | I, JOHN ARNDT, a Certified Shorthand |
| 4 | MR. O'CONNOR: Actually, it might be two | 4 | Reporter and Certified Court Reporter, do hereby |
| 5 | minutes. All right. | 5 | certify that prior to the commencement of the |
| 6 | MR. GOLDSTEIN: It's attorney two minutes. | 6 | examination, JOHN GILLIES was sworn by me to testify |
| 7 | EXAMINATION | 7 | the truth, the whole truth and nothing but the truth. |
| 8 | BY MR. O'CONNOR: | 8 | I DO FURTHER CERTIFY that the foregoing is a |
| 9 | Q. Mr. Gillies, earlier today you provided | 9 | true and accurate transcript of the proceedings as |
| 10 | testimony in response to questions from Mr. Ko about | 10 | taken stenographically by and before me at the time, |
| 11 | discussions with DEA concerning the abuse potential of | 11 | place and on the date hereinbefore set forth. |
| 12 | hydrocodone and hydromorphone; correct? | 12 | I DO FURTHER CERTIFY that I am neither a |
| 13 | A. Yes. | 13 | relative nor employee nor attorney nor counsel of any |
| 14 | | 14 | of the parties to this action, and that I am neither a |
| | Q. And you recall Mr. Ko's questions asked | | |
| 15 | about those two products together? | | relative nor employee of such attorney or counsel, and |
| 16 | A. Yes. | 16 | that I am not financially interested in this action. |
| 17 | Q. Are you aware of any discussions with the | 17 | |
| 18 | DEA about the abuse potential of hydromorphone in | 18 | |
| 19 | particular? | 19 | |
| 20 | A. No. | 20 | JOHN ARNDT, CSR, CCR, RDR, CRR |
| 21 | Q. In preparing for today's deposition, you | 21 | CSR No. 084-004605 |
| 22 | reviewed materials related to Mallinckrodt's national | 22 | CCR No. 1186 |
| 23 | suspicious order monitoring program; correct? | 23 | |
| 24 | A. Correct. | 24 | |
| | Page 327 | | Page 329 |
| 1 | Q. And you also reviewed materials relating | 1 | |
| 2 | | 2 | I, JOHN GILLIES, the witness herein, |
| 3 | | 3 | having read the foregoing testimony of the pages of |
| 4 | A. Yes, our program is national. | 4 | this deposition, do hereby certify it to be a true and |
| 5 | Q. Does that suspicious order monitoring | | correct transcript, subject to the corrections, if any, |
| 6 | program apply in the State of Tennessee? | 6 | shown on the attached page. |
| 7 | A. It would. | 7 | shown on the attached page. |
| 8 | Q. And do the other anti-diversion controls | 8 | |
| 9 | _ | 9 | |
| | you discussed today also apply in the State of Tennessee? | 10 | |
| 11 | A. Yes. | 11 | JOHN GILLIES |
| 12 | | 12 | JUNIN GILLIES |
| | MR. O'CONNOR: All right. That's all I | 13 | |
| | have. | | Community 1 to 1 C |
| 14 | MS. HERZFELD: You're free to go. | | Sworn and subscribed to before me, |
| 15 | MR. O'CONNOR: You want to go off the | | This day of, 201 |
| | record? | 16 | |
| 17 | THE WITNESS: We're all free to go. | 17 | |
| 18 | THE VIDEOGRAPHER: We are going off the | 18 | |
| 19 | record at 6:07 PM. | 19 | Notary Public |
| 20 | | 20 | |
| 21 | [SIGNATURE RESERVED.] | 21 | |
| 22 | | 22 | |
| 23 | | 23 | |
| 24 | | 24 | |

Case: 1:17-md-02804-DAP Doc#: 3013-11 Filed: 12/18/19 85 of 85 PageID#: 446076 Highly Confidential ty Review

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